Supplemental #2 (Original)

Intrathecal Care Solutions, LLC dba Advanced Nursing Solutions (ANS)

CN180~~6~~019

CN1804-019

Supplemental #1, and #2, ~~ther~~ were turned in together.

INTRATHECAL CARE SOLUTIONS, LLC DBA ADVANCED NURSING SOLUTIONS
Responses to Supplemental Questions #1

1. **Section A, Applicant Profile, Item 2**

   The Letter of Intent notes the contact person for the proposed project is Pam Carter while the application notes the contact person is Dejarnette Trice. Please clarify which contact is correct.

   The contact person for the project is DeJarnette Trice.

2. **Section A: Executive Summary (1) Description**

   Please provide a list of States Advanced Infusion Solutions (AIS), and Advanced Infusion Care, and/or Advanced Nursing Solutions currently provides intrathecal and immunological infusion nursing services in patients' homes and/or intends to in the future.

   Advanced Nursing Solutions ("ANS") provides nursing services in the following states: Arizona, Alabama, Georgia, Indiana, Kansas, Kentucky, Louisiana, Missouri, Mississippi, Ohio, Oregon and Washington. ANS anticipates providing services in South Carolina in the near future. ANS projects that business needs will require expansion into the following states within the next two years: Texas, Illinois, California, Michigan, New York, West Virginia, North Carolina and Arkansas. Advanced Infusion Solutions ("AIS") is licensed in every state in the country and has provided intrathecal pharmaceutical drugs to patients in every state. Currently, the Advanced InfusionCare provides immunoglobulin drugs to patients in Georgia, Alabama, Florida and Mississippi. Advanced InfusionCare anticipates receiving pharmacy licenses in two Texas, Illinois, California, Michigan, New York, West Virginia, North Carolina and Arkansas to support the business needs of ANS.

   It is noted AIS has compounded specialty pharmaceuticals and shipped those drugs to Tennessee so patient's implanted intrathecal infusion pumps could be refilled. Please indicate which home health agencies in the past refilled those patients' intrathecal infusion pumps in each of the 95 Tennessee Counties.

   AIS is not privileged to information that shows which home health agencies refilled patients' intrathecal infusion pumps. Historically, AIS did not coordinate with the physicians to provide nursing services. The pharmaceutical services were the only services provided in the state, and patients and their healthcare providers arranged pump refills for the patients. This certificate of need is being submitted to simplify the infusion refill process so providers and their patients can have the option to use one provider for both pharmacy and nursing services.

   Please indicate if the applicant's current pharmacy has an existing contract with a Tennessee Home Health Agency to refill implanted intrathecal infusion pumps. If so, please provide the name of the home health agency and the reason why that won't suffice.

   No, neither AIS nor ANS has an existing contract with a Tennessee home health agency to refill implanted intrathecal infusion pumps.

If an existing home health agency has a nurse with the Certified Registered Nurse Infusion Designation (CRNI) that administers the first infusion dose, would the patient need to be transitioned to the applicant in order to refill the implanted intrathecal infusion pump?

The pump must be filled with medication when the pump is surgically implanted into the patient. After the initial dose, the physician determines the plan of care. The appropriate setting of refills (i.e., in doctor's office or in the patient's home) is a decision made by the physician and patient. If the pump is refilled in the doctor's office, any nurse providing the service must be specially trained and competent to provide intrathecal pump care. If a home setting is ideal, the patient would be transitioned to ANS in order to refill the intrathecal infusion pump.

Please indicate the shelf life of the infusion dosages.

We use Beyond Use Dating (BUD) as follows based on the compounding risk levels of the prescriptions:

1. Non-compounded drugs: Expiration date per manufacturer's recommended storage conditions.
2. BUD for Low Risk Compounding: 48 hours at room temperature OR 14 days refrigerated per USP chapters
3. BUD for Medium Risk Compounding: 30 hours at room temperature OR 9 days refrigerated per USP chapters
4. BUD for High Risk Compounding: up to 45 days at room temperature (Extended stability, Stability Indicating Methods, Container Closure Integrity, pH, sterility, endotoxins and potency studies are done on file, aseptically prepare each patient specific drugs and are terminally sterilized using 0.2micron filters and autoclaved by steam heat)

Immunoglobulin shelf life is based on manufacturer's recommendation but is typically between 12-16 months.

Does the applicant use common overnight carriers to deliver the product to patient homes or is the dose delivered via nurse? Please explain.

For diversion purposes, in most cases the nurse receives the medication on behalf of the patient. The nurse has to sign for delivery, which is recorded in the company's system. The medication is overnighted to the nurse via UPS delivery. The medication is securely stored in a company issued biometric safe until the scheduled time of the refill.

Does the applicant propose any future branch offices?

Based on the nature of our business, there is not a need for branch offices. Nurses will always travel to patients to provide infusion services. No patients will be seen at the parent office location. Our nurses will be dispatched from their personal homes and will provide services within the driving time and distance requirements. The home office will serve as a hub for business operations, record-keeping, office space, etc. However, ANS will propose a future branch office if the need arises.

What is the current process of refilling Tennessee home health patients' intrathecal infusion pumps from pharmaceuticals provided by Advanced Infusion Services?

Currently, AIS only provides pharmaceutical services to physicians and patients in Tennessee. Refill management has been the responsibility of the physician.

Please provide responses for each item that follows:

A. **Please describe the process planned for compounding/preparation, shipping, delivery and safeguard of medications. Please describe who will be receiving the medications and the method of safeguarding shipment of same. Please also identify the name, address, license #, etc. of the pharmacy that will support the proposed Advanced Nursing Solutions application in Tennessee.**

AIS receives an order from the physician. Orders will be documented on any of the Advanced Infusion Solutions prescription order forms, or other legally acceptable form or prescription pad provided by the physician.

Prescription orders will be taken or verified by an AIS pharmacist directly with a physician or physician's office delegate prior to dispensing. The pharmacist will only accept and dispense prescription orders from a physician or nurse practitioner who is legally licensed to write prescription orders.

The medication is dispensed based on the patient-specific prescription. For home refill patients, the medication is sent to the nurse on behalf of the patient by overnight UPS shipping. For office use, the medication is sent to the physician's office on behalf of the patient by overnight delivery. The nurse has to sign for delivery, which is recorded in the company's system. The medication is overnighted to the nurse via UPS delivery. The medication is securely stored in a company issued biometric safe until the scheduled time of the refill.

Bond Pharmacy, Inc. dba Advanced Infusion Solutions is the pharmacy that will provide pharmaceutical services necessary for the intrathecal infusion refills. AIS is located at 623 Highland Colony Parkway, Suite 100, Ridgeland, MS 39157. AIS's TN pharmacy license number is 0000004688. See **Attachment 1 – AIS Tennessee Pharmacy License**.

B. **Should a patient served by Advanced Nursing Solutions require home health services for conditions other than those related to the intrathecal pump home infusion products, how does the applicant intend to respond to these needs across all counties of Tennessee based on a staff of six registered nurses in Year 1? Will these services be provided directly by the applicant's nursing staff or will the applicant seek to refer the patient out to another licensed home health**

agency to provide the skilled nursing care not related specifically to the infusion service?

Initially, ANS will ensure physicians understand that ANS only offers intrathecal and immunoglobulin infusion services to patients. ANS will advise physicians that home health agency services unrelated to the specific infusion services should be arranged with another home health agency. ANS nurses will always consult with physician and coordinate referrals as needed with home health agencies that offer a broader spectrum of home care services to meet the patients additional home care needs. ANS understands that our services are part of a larger plan of care for the patient, and ANS will actively participate and communicate with all providers that help ensure successful outcomes for patients.

C. Please define specific types of services patients are likely to require and discuss what special needs and care the patient and/or caregiver will require for the proposed skilled nursing intrathecal pump re-fill services. In your response, please identify those the minimum skilled nursing activities that must be provided as a condition of HHA licensure in Tennessee such as taking & recording patient vital signs and drawing blood and other fluids for lab tests.

The specific services for intrathecal care are all related to the management of the intrathecal pain pump. The specific services for the management of Ig therapy are related to immunologic disease states.

The skilled nurse will assess the patient comprehensively (review of all systems, vital signs, focus on systems that are identified in diagnosis such as pain, spasticity, infectious disease assessment, etc.). Patient rights and responsibilities, HIPAA, infectious disease, and emergency preparedness are all a portion of the admission documentation. Nurses will collect lab specimens related to the disease state and under the direction of the physician. The lab specimens are sent directly to the lab. The nurse will identify the patient's problems. Problems may include ongoing pain, new or changes in pain or spasticity, fever, sleeping habits, appetite, bladder/bowel concerns, mood/depression, caregiver support, fall risk and such. With the patient the nurse will determine the achievable goals and work toward the attainment of these goals. The patient's plan of care (POC) is a collaborative effort with all members of the healthcare team. This includes the patient, physician/prescriber, nurse, pharmacist, and family/caregivers. The CMS 485 is the foundation for the POC. The POC is implemented and assessed with each skilled nursing visit. The Communication to prescriber/physician is ongoing. Notes and requested documents are sent to the physician following visits. For urgent or matters requiring intervention, a call is placed to the physician and the POC is updated. Should additional services be required for the patient, the nurse works collaboratively with the physician/prescriber and coordinates the services to completion.

Patients with immunoglobulin receive one-on-one nursing care during the entire course of the infusion and post-infusion as per physician orders. Sub-cutaneous Ig patients receive a skilled nursing visit twice annually to assess the self-administration and knowledge deficits in self administration. Patient teaching and coaching is completed. Physician/prescriber is notified with nursing assessment documentation.

D. Please clearly identify the responsibilities of the patient's physician, the pharmacy that will be contracted to support the HHA's specialty infusion services (including compounding pharmacy, if applicable), the home health agency (including administrator, director of nurses and home infusion RN), and any others associated with the care of the patient for intrathecal pump refill. .

The physician/prescriber directs the patient care via orders. Company representatives provide the coordination of care between the patient, physician/prescriber, pharmacist, hospice agencies, skilled nursing facilities and other home health agencies providing the patient with continuum of care. The primary nurse and the intake department at headquarters oversee the coordination of care for each patient on an individual basis. The pharmacy will obtain a prescription from the patient's practitioner or managing physician with each order and or change in medication. The pharmacy care plan is created and managed by the registered pharmacist in collaboration with the nursing team.

The professional pharmacy staff maintain the standard of care as described by professional specialty organizations. These may include but are not limited to:

- Food and Drug Administration (FDA)
- Centers for Medicaid and Medicare Services (CMS)
- Occupational Safety and Health Administration (OSHA)
- Drug Enforcement Agency, Department of Justice (DEA)
- American Society of Health System Pharmacists (ASHP)
- Accreditation Commission for Health Care (ACHC)
- Centers for Disease Control and Prevention (CDC)
- State Boards of pharmacy

Upon the initial home visit, the intrathecal or infusion nurse will make the determination if prescribed services can be adequately provided at the patient's place of residence. If services cannot be provided, patient and physician will be notified at the initial evaluation. All patients receiving care from the company will have a written Plan of Care, reviewed and signed by their physician upon admission and with changes to therapy. Patients receiving opioid and non-opioid therapies will be reviewed according to state guidelines and requirements.

Coordination of Care documentation includes the following:

- Plan of Care (POC), includes the current physician's orders, with ongoing input from pharmacy and nursing team and the patient's summary of care for services provided by the infusion nurse. This includes the response to therapy, during the last certification period (i.e. 30 or 60 days) for review

- Nursing visit documentation is required for each visit. Case management and coordination of care is provided with pharmacy team. The pharmacy plan of care is developed by a qualified Pharmacist and followed for each patient. Upon assessment of any change in patient's status that may require physician intervention, the intrathecal or infusion nurse will notify the physician and/or authorized agent. If verbal orders are received the AIS nurse will document orders and send to physician for signature. When company representative receives notification of patient status changes from other agencies regarding intrathecal therapy, the AIS nurse will assess and discuss with the ordering physician and/or authorized agent. All verbal communication regarding

patients is documented in the Progress Notes adhering to the confidentially policy. Physicians, patients and other agencies involved with patient's care are provided with 24-hour availability of staff and contact information.

E. Has the applicant collaborated with existing HHAs and state professional HHA association(s) to identify and assess the need for its specialty infusion pump re-fill services? Were any existing service providers identified in the assessment? If so, why aren't these arrangements working in TN? Please describe the applicant's planning and research efforts in this regard in preparing for the development of its certificate of need application. In your response, please include any documentation from representatives indicating their participation in preparing an assessment of the need for the proposed HHA.

ANS has not collaborated with existing HHAs nor associations in its assessment to seek a home health agency license in Tennessee. Based on the company's independent assessment, internal data (i.e., number of pharmaceuticals shipped to patients in Tennessee) and feedback from healthcare providers, a need for additional intrathecal and immunoglobulin home health providers that have our competency and level of training in the intrathecal and immunoglobulin space is needed in Tennessee. Our company believes that continuity and coordination of care is optimally achieved for the patient when the physician does not have to search for an appropriate home health agency that can provide the specialized services to patients in a home setting. If ANS receives a home health agency license, patients and physicians who currently use our pharmacy services can also arrange for nursing services at the same time, thus eliminating the additional time it takes an office to find a home health agency qualified to provide intrathecal and immunoglobin infusion specialty services.

There are existing services providers that provide similar services. However, providers are limited in number. First, some may provide similar services but its business model is not primarily infusion services. Second, the companies that only offer intrathecal and immunoglobulin infusion services are limited in number, and the market will not become overly saturated by the entrance of additional companies that offer these limited services. See **Attachment 2: List of HHA Providers Offering Infusion Services** a list of home health agencies offering similar services. Support letters from Tennessee practitioners are provided as an attachment to this supplemental submission (**Attachment 11: Tennessee Providers Requesting Additional Home Care Service Agencies**).

F. Please provide brief descriptions of the following: (1) how potential diversions will be handled such as those that could involve the loss or theft of controlled substances; (2) the level of physician involvement in the provision of services to the proposed home health agency's patients; (3) the technology to be used to facilitate the nursing service across the entire state such as the use of video conferencing during in-home patient visits.

(1.) All potential diversions will be resolved in accordance with company policy and procedure and state and federal law. First, the nurse has to sign for the delivery of the medication. Next, it is the company's policy that nurses securely store drugs in a biometric safe to decrease the likelihood of diversion by a third party. However, in the event of a potential diversion, nurses will immediately alert the home health agency administrator and the pharmacy director. All parties will determine when the chain of custody was broken and investigate how the drug could have been diverted by another party. The authorities will be alerted if necessary. Also, nurses receive drug testing annually and for cause.

The programmer also serves as an additional safety mechanism sine the device monitors access to the pump. Upon each nursing visit, the pump is interrogated and the nurse verifies who last accessed the pump programming. Any access that falls outside of the official cycle is investigated. As for the telemetry, the company uses a dual signature model to prevent diversion of wasted drugs.

(2.) Physicians are involved with the home care process as well. ANS will only perform intrathecal pump refills as per the physician's order and plan of care. The dose of medication, frequency of refills and any additional programming is solely determined by the patient's physician. ANS helps the physician carry out his/her plan of care for the patient, and the physician is involved in the process.

(3.) ANS uses a coordinated care model with the patient's physician to achieve optimal health benefits for the patients. The coordinated care model includes the use of several technology components including:

a. The manufacturer pump programmer validates pump access. Access can be reviewed via a telemetry report.

b. A secure web portal accessible 24 hours a day, 7 days a week by the physician, pharmacy, and ANS that contains current orders, prescriptions, nurse assessments and telemetries, order history and all other patient records.

The company offers 24-hour on call access to administrator/nurse in the event of an emergency. The program's goal is to drive optimal healthcare outcomes by providing:

- Patient Care Coordination – timely, efficient, safe, and patient-centered care
- Proactive care planning to drive positive health outcomes
- Monitoring and reporting the patient's response to treatment, identifying potential gaps, and providing communication to the treating physician/prescriber
- Maintaining the continuum of care within patient's healthcare team
- Managing transitions of care and long-term condition support
- Assisting with psychosocial support
- Increasing patient engagement through education and communication
- Reducing healthcare costs

Coordination Services Include:

- Nursing Services (Patient and Physician)
- Optimization and risk assessments

- Proactive patient intervention
- Pharmacy coordination of care and consultation
- Pain/Spasticity Disease and Care Management
- Reimbursement support
- Customer Service Representatives
- Refill reminders
- Appointment reminders
- Data and Outcomes
- Nursing Services (Patient and Physician)
- Optimization and risk assessments
- Proactive patient intervention
- Pharmacy coordination of care and consultation
- Pain/Spasticity Disease and Care Management
- Reimbursement support
- Customer Service Representatives
- Refill reminders
- Appointment reminders
- Data and Outcomes

G. Please discuss how the applicant intends to develop, manage, implement, supervise and maintain patients' plans of care, including plans to manage patient pain.

The process of developing the medical Plan of Care is based on professional staff assessment of the patient's immediate and long-term needs, in consultation with the prescriber and healthcare team. An RN will make the initial evaluation visit and the patient's Plan of Care. An RN will reevaluate the patients nursing needs and make adjustments to Plan of Care as needed and at least every 62 days.
It is the physician/prescriber's responsibility for authorizing in writing all care, medications and treatments that will be provided. The Plan of Care will be sent to prescriber every 30 or 60 days (not to exceed 62 days) for review and signature. Patients receiving opioid therapies will be reviewed every 30 days; non-opioid patients will be reviewed every 60 days by the ordering physician.
The pharmacist provides support and guidance for the nursing team regarding prescriptions. Prescription recommendations are discussed in internal telephonic or written care conferences and provided to physicians as needed.
Prescriber orders are required to provide any services requiring the administration of medication, treatment(s), and ongoing assessments. Each Plan of Care will show evidence of the patient's participation in the plan development and any changes in the plan. Each POC is reviewed for the following:

- Current physician's orders
- Appropriateness (still needed)
- Effectiveness (patient response to care)
- Patient/caregiver satisfaction level
- Diagnosis
- Allergies
- Patient problems/goals/outcomes
- Activity/Functional limitations
- Safety measures

Updated Plans of Care will be completed yearly or at the request of the practitioner.

H. Please identify the owner's experience in other states and identify any active licenses. Please also note the status of Medicare/Medicaid certification and accreditation. A suggested template to use is provided in the table below.

See **Attachment 3 (Pharmacy Licenses)** and **Attachment 4 – (Home Health Licenses)** for a list of all licenses for the pharmacies (Advanced Infusion Solutions and Advanced InfusionCare) and home health agency (Advanced Nursing Solutions).

I. What is the specific staff training/experience to be required for this type of service as it applies to clinical staff (RNs/DON), the administrator and 24 hour call center staff of the proposed HHA?

The company ensures that ongoing and annual training/competencies/skills performance is completed for all nursing staff. This includes regularly scheduled in-service programs and opportunities for continuing education.

The nursing director and administrator take reasonable steps to ensure that services are available, care/services provided by agency personnel and contracted agency personnel are coordinated and integrated, policies and procedures, which guide and support the provision of care/services are developed, updated, implemented and distributed to staff and recommendations for resources needed are made. The supervision of clinical care/services is available twenty-four hours a day, seven days a week.

The director is responsible for the oversight of daily nursing operations through consultation and collaboration with the pharmacy and other operational staff. The director has access to qualified clinical consultation for services outside his/her expertise, through the use of pharmacists, Medical Director and/or other resources as appropriate

Competency validation is verified by supervisor or trainer observation in the work environment, through manufacturer or company in-servicing, and to include supervisor/trainer personal "check off" of skills. Each nurse will be observed performing a pump refill or an IVIG infusion yearly in the practice setting. Each infusion nurse will be observed performing infusion services yearly in the practice setting. No nurse will be independent with the procedure until the competency validation is obtained. Pump and medication procedures vary with each manufacturer. Each brand of pump and medication will require validation and competency based on the location and service. Intrathecal and infusion nurses will demonstrate knowledge, skills, behaviors, and ability to perform the assigned job.
The introduction of new technology or equipment will require separate competencies.

Annual competency/educational refresher course led by the company's Nursing Director, Trainer or manufacturer representative will be conducted. Examples of annual competencies and in-services are below:

- Medtronic skills lab and check-off competency
- Flowonix skills lab and check-off competency
- Infusion and CADD pump training
- Medication Information Sheets for patients review training
- Handwashing skills checkoff
- Sterile field competency checkoff
- Vehicle and bag inspection annually and will field rides (Supply checklist, universal precautions, etc.)
- Standards of care for infusion therapy and care (INS Standards and IgNS Standards)
- Universal Precautions Training
- Emergency Procedures Training
- Pharmacy Training Modules (Medication specific for IT and infusion)
- Corporate Compliance and Code of Conduct Training
- Policy, Procedure and Form review
- Refill check-off and competency
- Spasticity Assessment training
- Pain Assessment training
- Falls Risk Assessment training
- Equipment validation and replacement
- TB testing
- License renewal
- CPR Certification
- Care and maintenance of infusion access
- Quality Process Improvement
- Computer Skills/Use of Surface Pro/LYNX/CPR+
- Nursing Orientation
- Home Health Licensure/Survey Readiness
- PHI/HIPAA
- Conflict of Interest discussion
- Grievance/Complaints and how to report and FU.
- Abuse and Neglect Training
- Advance Directives
- Ethics Training: Potential ethical issues and process to follow when identified.
- Cultural Awareness Training
- Competence and Competency Training Skills check)
- Emergency Disaster Training
- Infection Control

- Communication Barriers
- Workplace and patient safety (OSHA)
- Patient Rights and Responsibilities
- Compliance Program
- Field coaching report
- PI Activities
- Blood born pathogen
- OSHA
- TB Exposure
- Bio-hazard training

See **Attachment 5: Call Center Training** details training requirements for call center representatives.

J. Please explain the rationale for a parent office without any branch offices located in the applicant's proposed 95 county state-wide service area. In your response, please address how this complies with existing HHA licensing requirements such as might apply to branch offices centrally located within a 100-mile radius of service area population in distinct geographic areas, within specific driving times or distance requirements, and proximity to access to a sufficient workforce such as nursing staff for skilled nursing services, etc.

No patients will be seen at the parent office location. Our nurses will be dispatched from their personal homes and will provide services within the driving time and distance requirements. The nature of intrathecal infusion and immunoglobulin therapy services is different than what can be expected from traditional home health agencies. Most intrathecal patients require a refill over an extended period of time, thus eliminating scheduling constraints for the number of staff we anticipate hiring. The immunoglobulin therapy is a cyclical and consistent schedule so that we can anticipate long-term scheduling needs. Therefore, we can offer intrathecal infusion and immunoglobulin therapy services in every county in Tennessee during our initial year of operation. The home office will serve as a hub for business operations, record-keeping, office space, etc. However, the home office is not necessary in order to provide intrathecal and immunoglobulin services, as nurses will drive to the patient's home.

Please briefly describe a typical visit – include length of time, standard services covered, frequency of visits with physician, how refill orders are processed, and how other services that may be needed will be provided (e.g. homemaker aide assistance).

The typical home skilled nursing visit varies depending on the patient need and physician/prescriber orders.

Intrathecal refill visits typically last 45-60 minutes. The full nursing assessment, interrogation/assessment of the pump, medication refill and reprogramming are all a part of the standard visit. In some cases, the physician/prescriber orders the nurse to simply make an adjustment in dosing on the medication. In this case, the nurse would complete all of the above actions, except for the medication refill. An important aspect of this refill visit is a "real time telemetry" validation. When a home nurse makes any adjustment to the programmed pump, while in the patient's home they must send the telemetry report to headquarters. Another qualified RN reviews the program and medication settings in real time and before the nurse leaves the patient. This is much like the protocols for high risk product in the hospital setting.

For immunoglobulin patients the visit can last 2-8 hours[1], depending on the physician orders and the medication prescribed. The nurse conducts a full nursing assessment of all systems before starting the infusion. The nurse remains with the patient during the entire infusion, monitoring for any reactions, checking vital signs, infusion site and patient response. Protocols and orders are in place to guide the nurse in responding clinically to any reaction the patient may experience. The physician office or emergency services are contacted immediately for any urgent needs based on the nursing assessment of the patient.

In all cases, the driving factor is the physician order. Within in the nursing scope, the nurse follows this plan of care established by the prescriber/physician and the healthcare team.

Should additional services be required, the skilled nurse is responsible to contact the physician/prescriber. From their assessment, they communicate with the office to inform them of the patient need. The physician and patient choose the home care company to provide these other services. A communication note and the plan of care is shared with the physician's office and if appropriate, with the new service provider.

Patient office visit are established by the clinic. The nurse reminds and reviews upcoming appointments with the patient for the physician appointments and for the next home visit.

The company's care coordination center engages the intrathecal patients between refill visits to conduct nursing tele-health assessments for the patient based on a risk assessment. Typically, these interventions are conducted 3-days following a refill, 2-weeks before a refill and mid-cycle based on patient's risk assessment. A clinical report is sent to each physician following the interaction. If urgent or immediate intervention is required, the care coordination nurse contacts the physician/prescriber real time via phone to share assessment.

3. Section A: Executive Summary, Rationale for Approval (2) Economic Feasibility

It is noted by the applicant there are physicians who are currently performing refill and infusion services in their offices that has a desire to transfer care to the patient's home. Please clarify if the applicant plans to provide letters of support and/or referral

[1] ANS projects most of its business will result from intrathecal infusion patients in Year 1 and Year 2 which supports an average one-hour per visit patient visit.

from those physicians. Yes, see **Attachment 6 – Tennessee Providers Requesting Additional Home Care Service Agencies**.

4. **Section A, Project Details, Item 6.A. Legal Interest**

   The month to month site agreement is noted. However, please provide a fully executed Option to lease agreement or other appropriate documentation that includes the actual/anticipated term of the agreement and actual/anticipated lease expense.

   Attachment 7: Lease and Renewal of Lease provides a copy of the original lease and renewal lease. The original lease was electronically signed as evidenced in the attachment. Also, ANS anticipates entering into a one-year lease beginning July 2018. The terms of the renewed lease may not be final at this time; therefore, a draft copy of the lease is attached. However, a copy of the renewed lease will be provided upon execution by both parties.

5. **Section A, Project Details, Item 6.B.1 (Plot Plan) and 6.B.2**

   As required for all projects, a Plot Plan must provide the size of the site (in acres), location of the structure on the site, the location of the proposed construction, and the names of streets, roads, highways that cross or border the site. Please provide a Plot Plan with all the required information.

   The floor plan is noted. Please clarify which floor the applicant will be located.

   ANS is located on the third floor.

   Please provide a description of the proposed Nashville home office including its size (e.g. ability to accommodate staff of the HHA and a 24-hour call center) and cost. In your response, please also discuss the operation of the 24-hour call center including staffing (salary/ wage personnel or contract service) and the call center's primary means of communication with patients and attending physicians. Will call center personnel work on-site or at a remote location (if off site, please specify site address)? Please clarify.

   The Nashville home office is less than 500 square feet and is intended for home care staff usage only. It is located at 555 Marriott Drive, Suite 315, Nashville, Tennessee. The field-based nurses are available to the patient 24 hours/day, 7 days/week by phone.

   See **Attachment 8 – Office Space Description.**

   The 24-hour call center is located at 18451 Dallas Pkwy, Suite 150, Dallas, Texas 75287. The center is approximately 10,000 square feet and is staffed by nurses, customer service representatives, pharmacists and reimbursement. Hours of operation are 7:00 a.m. – 6:00 p.m. Monday – Friday. Nursing staff are available to patients

and physicians on-call after hours, weekends and holidays. The staff are all direct full-time employees of the company. Nursing salaries range from $29-$36/hour. The customer service representative salaries range from $19-$21/hour. The pharmacist salary is $115,000 annually. The primary means of communication is via telephone, fax or secure email.

Please explain the rationale for a parent office without any branch offices located in the applicant's proposed 95 county state-wide service area. What consideration was given to locating branch offices in distinct geographic areas, in order to reduce driving times or distance requirements, and ensure access to a sufficient workforce such as nursing staff for skilled nursing services?

No patients will be seen at the parent office location. Our nurses will be dispatched from their personal homes and will provide services within the driving time and distance requirements. The nature of intrathecal infusion and immunoglobulin therapy services is different than what can be expected from traditional home health agencies. Most patients require a refill over an extended period of time, thus eliminating scheduling constraints for the number of staff we anticipate hiring. The immunoglobulin therapy is a cyclical and consistent schedule so that we can anticipate long-term scheduling needs. Therefore, we can offer intrathecal infusion and v therapy services in every county in Tennessee during our initial year of operation. The home office will serve as a hub for business operations, record-keeping, office space, etc. However, the home office is not necessary in order to provide intrathecal and immunoglobulin services, as nurses will drive to the patient's home.

6. **Section A, Project Details, Item 9 Medicaid/TennCare Participation**

Please discuss the reason the applicant has chosen to not provide in-home intrathecal and immunological infusion nursing services to TennCare and Medicare patients. Is the service generally a covered service under these payor groups? Please discuss.

Home health agencies are required to be Medicare-certified in order to enroll in TennCare. ANS is not Medicare-certified and does not anticipate seeking Medicare certification in the future. Therefore, our services would not be covered under Tenncare.

Additionally, Medicare does not traditionally cover infusion services administered by a nurse in the home.

Please clarify if TennCare and/or Medicare enrollees will be provided infusion services as out-of-network or under some other arrangement.

ANS will evaluate patient needs on a case-by-case basis to determine whether arrangements can be made to cover the cost of the nursing services. In some instances, ANS may be able to partner with physician to provide in-office intrathecal and immunoglobulin services if home health is not an option.

If the applicant does not plan to provide intrathecal home infusion nursing services to TennCare/Medicare enrollees, where would enrollees be referred for those services?

If a Medicare-certified home health agency is required, ANS would refer patient back to the physician in order for physician to select the appropriate Medicare-certified home health agency.

If a home health provider is not located, would an enrollee be required to travel on-site for infusion services? Please be specific.

Yes, and ANS would consider providing the services in the physician's office if necessary.

What home health providers in Tennessee do TennCare and Medicare patients receive in-home intrathecal and immunological infusion nursing services?

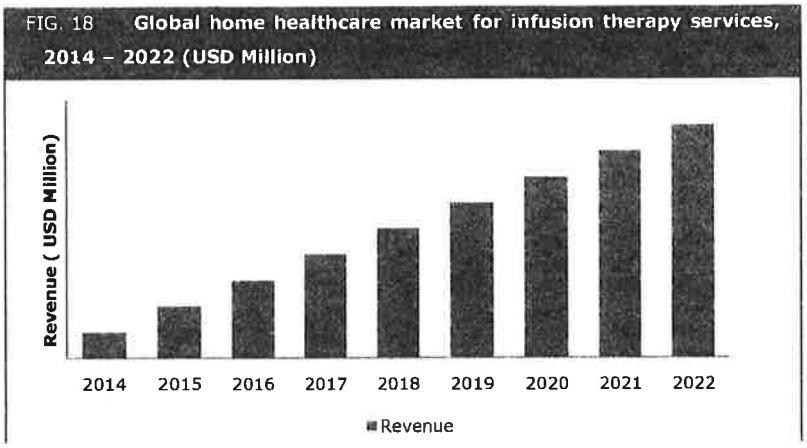
Since reimbursement under Medicaid and Medicare is limited for home infusion nursing services, there may be a limited number of home health agencies that can provide services to applicable patients. These services would have to be provided on a charitable basis.

7. **Section B. Need, Item 1 (Specific Criteria: Home Health Services)**

It is noted the applicant the applicant did not list each question of the home health criteria and standards and a response directly underneath each question. Please list each question of the home health criteria and standards and provide a thorough response directly underneath each numbered question. The Project Specific Home Health Criteria may be found at the following web-site: https://www.tn.gov/content/dam/tn/hsda/documents/Home_Health_Services_Criteria.pdf

The global home healthcare infusion market is mainly driven by increasing geriatric population, rising healthcare costs and technological advancements in healthcare devices. With rising health awareness among people and an increasing number of people diagnosed with chronic, rare and immunological diseases, the demand for home healthcare market is expected to grow in the near future. The population of geriatric people is growing rapidly across the world. Rapid job growth in home healthcare services is expected in open alluring avenues for the market growth over the next few years.

(https://www.zionmarketresearch.com/sample/home-healthcare-market)



The National Institutes of Health ("NIH") estimates that approximately 100 million Americans suffer from chronic pain. Among these chronic pain sufferers are nearly 25 million who say the pain is severe enough to impact their quality of life on a daily basis. Of those, the NIH estimates that nearly 10 million take opioids to manage their long-term chronic pain and over 2 million of those Americans are on a long-term regimen of oral opioids. Intrathecal pumps were introduced to the market in 1991 and have proven to be a safe and effective therapy for those patients suffering from both chronic pain as well as spasticity. Unlike the systemic delivery mechanism used by oral narcotics, intrathecal infusion uses targeted drug delivery which involves piercing the blood/brain barrier on the spinal column to insert a catheter through which a continuous infusion of pain medication is provided directly to the spinal area associated with the pain. While highly efficacious, there are substantial complexities associated with intrathecal infusions, including the need for highly trained and skilled clinicians.

(1) Determination of Need

See Joint Annual Report of Health Agencies – 2017 Final report (Attachment 9).
(Also Original Attachment: Section B- General Criteria for Certificate of Need -- A.)
The attachment shows a comparison of the population-based need projection versus the actual utilization for a period of three years (2017-2020).

The JAR reports project a need for additional home health agency services in Tennessee counties with the exception of Madison and Moore counties. Furthermore, while JAR reports measure the need for home health agency services in Tennessee, the reports do not directly indicate the need for our services, as the reports do not isolate limited and specialized intrathecal or immunoglobulin therapy services ANS offers. Therefore, it is difficult to determine gaps in service for Tennessee patients and whether current home health agencies provide intrathecal infusion services, which is a highly specialized and more complex infusion than most home health agencies provide.

Statistical data provided in the JAR reports may not accurately reflect patients' accessibility to intrathecal infusion services in their county. It is possible that the use rate of

existing home health agencies related to intrathecal and immunologic services is significantly lower, thus necessitating the need for additional services in the market.

Data collected from the Tennessee JAR reports (and the absence of isolated data related to our specialty type) as well as national growth trends in home infusion support the determination of need for our services in Tennessee. Please see Attachment: Section B-General Criteria for Certificate of Need--A.1 (for a list of competitors and A.2 (JAR Reports).

(2) Three-Year Need Projection

The latest available year of JAR report data is 2017. **Attachment 9: Joint Annual Report of Health Agencies – 2017 Final** report compares the population-based need versus the actual utilization to 2020. The JAR reports project a need for additional home health agency services in Tennessee counties with the exception of Madison and Moore counties. Again, while JAR reports measure the need for home health agency services in Tennessee, the reports do not directly indicate the need for our services, as the reports do not isolate limited and specialized intrathecal or immunoglobulin therapy services ANS offers. Since a limited number of home health agencies in Tennessee offer similar or same services, it is likely that the need for intrathecal and immunoglobulin infusion services is higher than need projections for traditional home health agency services.

(3) County Need Standard

For intrathecal infusion, referral sources may anesthesiologists, pain management physicians, neurologists and oncologists in the state of Tennessee; Worker's Compensation companies and their case managers will also likely refer patients. Most of these physicians are located in metropolitan areas which provide a larger patient base. Patients travel to these areas for services that are not provided in their local area. Our services will eliminate patients' need to commute from more rural areas to physicians' metropolitan-based office areas in order to receive nursing services.

For infusion and specialty care, referrals sources may include physicians practicing the following specialties: immunology, gastroenterology, hematology/oncology, infectious disease, internal medicine, neurology and family practice.

The services would be available to all residents of the geographic area as requested by their physician. Services are provided per physician's orders in the patient's home, skilled nursing facility, rehabilitation centers, infusion suites and other outpatient settings.

(4) Use Rate of Existing Home Health Agencies JAR reports show only 13 home health agencies indicated that infusion services were provided in 2017 (shown as "Infusion Therapy – Pain Management" and "Infusion Therapy – Other" JAR reporting categories). ANS is aware of two companies, Pentec Health and Implanted Pump Management, that offer the same services ANS is proposing to offer.

Statistical data provided in the JAR reports may not accurately reflect patients' accessibility to intrathecal infusion services in their county. It is possible that the use rate of existing home health agencies related to intrathecal and immunologic services is significantly lower, thus necessitating the need for additional services in the market

(5) Current Service Area Utilization

See Original Attachment: Section B-General Criteria for Certificate of Need--A.1 (List of Competitors)

See Original Attachment: Section B-General Criteria for Certificate of Need--A.2 (Jar Reports)

The JAR Reports provide data on home health agencies that are currently providing infusion nursing services. The list of competitors provides a detailed list of the number of patients seen by HHAs for Infusion Therapy - Pain Management and Infusion Therapy – Other in the following categories:

- **Patients Served and Gross Revenue By Revenue Source**
  - **TRICARE**
  - **Commercial**
  - **Pay**
  - **Home and Community Based Waiver Programs**
  - **TN Commission on Aging and Disability**
  - **Charity Care**
  - **Federal Department of Labor (EEOICP)**
  - **Other**
  - **Total All Revenue Sources**

As previously mentioned, while the JAR reports show that some Tennessee home health agencies provide some infusion services, it is difficult to determine whether these HHAs provide intrathecal infusion services, which is a highly specialized and more complex infusion therapy type. Therefore, the statistical data provided in the JAR reports may not accurately reflect patients' accessibility to intrathecal infusion services in their county. It is possible that the use rate of existing HHAs is significantly lower, thus necessitating the need for more services in the market.

(6) Adequate Staffing

ANS uses a variety of methods to recruit employees. The human resources department actively recruits candidates throughout the healthcare spectrum by utilizing job board advertisements, employee referrals, direct calling methods, and newspapers advertisements. The interviews and traits profile testing are conducted to ensure candidates are a great match for the position. A background check is a condition precedent before a candidate can on-board with the company. The on-boarding process includes orientation to the company, review of all policies and procedures, on-line classes and nurse specific hands-on training

with skill check validation. Ninety-percent (90%) of the qualified personnel will be direct employees for immunologic care and 100% will be direct employees for intrathecal care. The nursing division turn-over rate is six-percent (6%).

(7) Community Linkage Plan

ANS will be transfer or refer patients to alternative care entities when specifically, defined conditions exist. ANS will have agreements or arrangements with facilities to coordinate alternate care for patients as required. Agreements will meet the credentialing and training requirements of the entity.

Agreements and Arrangements will include the following:

a. Nursing services for in-patient or out-patient hospital, patient's home, long-term care facility, rehabilitation facility and hospice will be provided with written agreements

b. Specialized diagnostic services, such as an MRI facility, will be provided with written agreements.

c. Other home health agencies will be engaged to provide skilled or non-skilled patient care as required by patient need. Referral or transfer will be coordinated directly with agency and will be a patient specific referral or transfer of services.

d. Emergency medical services will be provided through 911 emergency system

e. Local health department arrangements will be instituted to report required infection or communicable diseases, as well as all state mandated reporting, such as abuse or neglect.

f. Pharmacy services for the intrathecal care will be provided by AIS. Alternate pharmacy services will be coordinated through the prescribing physician.

A written *Additional Services or Transfer Summary* detailing the services will be provided to the patient. This may include a summary of care, patient's current physical and psychosocial status, instructions provided to patient, current medication list, advance directives, any continuing symptom management needs, and reasons for transfer.

(8) TennCare MCO and Financial Viability

For business reasons, ANS has decided not to seek Medicare-certification in any jurisdiction. TennCare currently requires Medicare certification from all home health agencies in order to enroll, and thus, ANS is unable to enroll in the network.

ANS has financial viability and has enough cash reserve to fund this project.

(9) Proposed Charges

The average charge per skilled nursing visit is $175 for the first 2 hours and $100 for subsequent hours.

(10) Access

Our services will improve access to care for patients who need intrathecal or immunological infusion therapy services. Providing quality care services offered in the home increases access to care for these patients. Additionally, this can greatly benefit patients who do not live in close proximity of their doctor's offices, who do not have their own source of transportation or who do not have access to public transportation. With our services, patients do not have to worry about the potential logistical challenges associated with receiving their infusion refill in the physician's office.

(11) Quality Control and Monitoring

Quality control and monitoring is multi-faceted. The nursing Quality Performance Improvement (QPI) program includes patient safety, patient and HCP satisfaction, infection control and staff competencies.

See Original Attachment: Section B-General Criteria for Certificate of Need—A.3 (Quality Control & Monitoring)

(12) Data Requirements

ANS agrees to provide the Department of Health and/ or HSDA with all reasonably requested information and data related to our services offered under this certificate of need, in the time and format requested.

Describe the relationship of this project to the applicant facility's long-range development plans, if any, and how it relates to related previously approved projects of the applicant.

ANS's level of care to patients is a reflection of its motto – Patient. Care. First. Our long-term goal is to ensure that our infusion patients receive the care and attention they deserve. Home care patients appreciate the familiarity of the same nurses, and our business model accommodates patients in this manner. Patients routinely receive the same care from the same nurses. Additionally, we will partner with local physicians who prefer to have their patients' refills and infusions occur in the comfort of patients' homes. In doing so, we also invest in Tennessee by employing Tennesseans who provide services to patients in their own communities.

Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map for the Tennessee portion of the service area using the map on the following page, clearly marked to reflect the service area as it relates to meeting the requirements for CON criteria and standards that may apply to the project. Please include a discussion of the inclusion of counties in the Border States, if applicable.

ANS proposes serving all ninety-five (95) counties in Tennessee.

The need for broad service area is based in the fact that patients requiring these specialty services are located throughout the cities and counties across Tennessee. ANS must base our service location on the location of the patient, not the location of the physician's office. The aging population and need for home care are growing in both rural and metropolitan service areas. Many patients travel from rural areas to metropolitan areas to receive their infusion services in the physician's office. Therefore, it is impossible to pre-determine the location of each patient requiring our services, but we are willing to accommodate their needs in any county in which they reside.

8. **Section B. Need, Item 1 (Specific Criteria: Home Health Services) (1) Determination of Need**

   The listing of existing similar service providers in Attachment-A.1 is noted. Please provide a list of licensed counties covered by each home health agency.

   As per the TN Department of Health listing of Health Care Facilities, see **Attachment 10: Certified Counties for Existing Similar HHAs** for the counties in which the home health agencies are certified.

9. **Section B, Need, Item 1.a. (Project Specific Criteria-Home Health Services) Item #4 County Need Standard**

   Please provide letters from the 95 county proposed service area that demonstrates that there is a need for home health services in <u>each individual county</u> by providing documentation (e.g., letters) where: a) health care providers had difficulty or were unable successfully to refer a patient to a home care organization and/or were dissatisfied with the quality of services provided by existing home care organizations based on Medicare's system Home Health Compare and/or similar data; b) potential patients or providers in the proposed Service Area attempted to find appropriate home health services but were not able to secure such services; c) providers supply an estimate of the potential number of patients that they might refer to the applicant.

See **Attachment 11: Tennessee Providers Requesting Additional Home Care Service Agencies** for support letter ANS has received from practitioners in Tennessee.

10. **Section B. Need, Item 1 (Specific Criteria: Home Health Services) (5) Current Service Area Utilization**

    Attachment A.1 listing infusion therapy home health providers is noted. However, please revise the table to include Medicare and TennCare categories.

    See **Attachment 12: – Revised Section B. Need, Item 1 (Specific Criteria: Home Health Services) (5) Current Service Area Utilization.**

    Please provide a list of approved but unimplemented Certificate of Need Home Health projects specific to intrathecal and immunological infusion nursing services. Please include the project name, CON number, approval date, and counties in service area.

    See **Attachment 13: Certificate of Need Home Health Projects.** ANS has provided a list of home health agencies that submitted a certificate of need in 2015-2017. Based on the description of services, AlexaCare Health Solutions appears to be the only home health agency that may have approved but unimplemented certificate of need projects (additional counties added).

11. **Section B. Need, Item 1 (Specific Criteria: Home Health Services) (9) Proposed Charges**

    The applicant's proposed charges are noted. However, please compare the applicant's proposed charges to similar providers in the service area.

    See **Attachment 14: Fee Comparison – JAR Data.** The fees charged by home health agencies offering similar or same services ranges from $138-$275[2]. Our projected fee of $175 still falls within the range of services offered by same or similar home health agencies.

12. **Section B. Need, Item 1 (Specific Criteria: Home Health Services) (10) Access**

    It is noted the target population of this application is 18+ years. If granted, is the applicant seeking to restrict on condition to serving only the 18+ population? Please clarify.

[2] The JAR report indicates that Pentec Health's charge per visit is $275 for skilled nursing care. Pentec offers the same services ANS is proposing to provide.

No, there is no restriction on serving only the 18+ population. ANS can provide intrathecal services to any patient with an implanted pain pump and immunoglobulin nursing services are provided as per doctor's order. ANS chose the target population of 18+ to ensure we capture the age populations that typically requires our services.

13. Section B, Need, Item C –

Please complete the following tables.

See Attachment 15: Nursing Projection Utilization and Pharmacy Historical Utilization.

Service Area Counties	**Projected Utilization-County Residents**	**% of total procedures**
County #1		
County #2		
Etc.		
Total		100%

Please complete the following table indicating the number of intrathecal infusion refills that were shipped from Advanced Infusion Solutions to Tennessee patients in 2017 by county.

See **Attachment 15: Nursing Projection Utilization and Pharmacy Historical Utilization.**

Service Area Counties	**Historical Utilization-County Residents**	**% of total procedures**
County #1		
County #2		
Etc.		
Total		100%

14. Section B, Need, Item D.1 -

The demographic table in Attachment: Section B-Need-D.1. is noted. However, please complete the TennCare columns of the table and submit a revised table. See **Attachment 16: Revised Section B-Need-D.1.**

15. Section B, Need, Item E -

Describe the existing and approved but unimplemented services of similar healthcare providers in the 95 county service area (include Pentec Health, CN1411-046A and Implanted Pump Management, LLC, CN1407-027A). Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. List each provider and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: Admissions or discharges, patient days, average length of stay,

and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc. This doesn't apply to projects that are solely relocating a service.

See **Attachment 17: Existing Similar Healthcare Provider Utilization** which includes three years of historical utilization data for existing healthcare providers offering same or similar services. See **Attachment 13: Certificate of Need Home Health Projects.**

The 2017 data shows that infusion therapy is only a small portion of business for most of the home health agencies that provide some type of infusion therapy. The home health agencies are more traditional agencies also offering a wide variety of services to patients, including home health aide, medical social services, occupational therapy, speech therapy and physical therapy. The data shows that the following agencies reported less than one-percent (1%) visits/hours for infusion therapy services:

- Suncrest Home Health - Claiborne
- Cumberland River Homecare - Clay
- Suncrest Home Health - Davidson
- Home Care Solutions - Davidson
- Suncrest Home Health - DeKalb
- Procare Home Health Services - Greene
- Henry County Medical Center Home Health - Henry
- NHC Homecare - Maury
- Still Waters Home Health Agency – Shelby

While the attachment shows the remaining home health agencies reported providing some infusion services, the agencies do not cover all counties in Tennessee. This results in a potential gap in coverage for patients who could benefit from home care intrathecal and infusion services. As shown by the support letters provided in this submission, practitioners agree that additional home care services are needed in Tennessee.

Data derived from 2015 and 2016 agency reporting does not show the number of visits and hours home health agencies provided for infusion therapy. The agencies' visits and hours for infusion therapy is likely captured in the skilled nursing care category. Based on the minimal number of infusion therapy services reported in 2017, it is unlikely that infusion services provided in 2015 and 2016 reach significant amounts.

16. Section B, Need, Item F

Provide applicable utilization and/or occupancy statistics for your institution the projected annual utilization for each of the two years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions. Please refer to "Attachment Section B-Need-C.1 Potential Patients Based on Historical Data" only as support of your narrative response.

See **Attachment 18: Pharmacy Historical Utilization** which shows 2017 pharmaceutical utilization data for the pharmacy. The pharmacy provided services to 985 patients in 2017. The cluster map provided in the attachment demonstrates that AIS provided pharmaceutical services to patients in almost every county in 2017. The collapsed map further demonstrates that the penetration of use by practitioners and patients almost covers the entire state.

Nursing Utilization Projections: The attachment also provides the projected utilization for nursing services in the first two years of operation in Tennessee. ANS projects completing 304 home care visits for 101 patients in the first year of operation. The attachment shows the number of patients we project will use our services by county. The projection is derived from the number of patients that currently use AIS's pharmaceutical services. ANS anticipates providing home care nursing services to ten-percent (10%) of the patients currently using AIS's pharmaceutical services. Several practitioners in Tennessee support ANS providing home care services, as expressed in the letters ANS is providing with this submission. ANS anticipates providing nursing services to twenty-percent (20%) of patients affiliated with the practitioners.

ANS projects completing 614 visits for 112 Tennesseans who need infusion services by the second year of operation. This shows about a ten-percent (10%) increase in growth from Year 1, or eleven (11) additional patients. The additional patients will likely come from the metropolitan areas and surrounding counties where we have a large number of patients receiving our pharmaceutical services. ANS anticipates that future growth will continue to rise in more rural areas where access to care/travel distance to physician's office may be more burdensome for patients, thus increasing the need for home care services.

Attachment Section B-Need-C.1 (Potential Patients Based on Historical Data) was provided during our initial submission. The data was computed using a date range of January 1, 2017 through March 31, 2018. Some of the questions in the supplemental material specifically ask for historical utilization information for 2017. For consistency purposes, ANS also based its projected utilization in Year 1 and Year 2 by using 2017 pharmaceutical data and did not based its projects on the previously submitted data.

It is worth noting that the number of patients who receive pharmaceutical services has noticeably increased during the time span. The projected data shows that 975 patients used our services in 2017. The previously submitted Attachment Section B-Need-C.1 (Potential Patients Based on Historical Data) shows that 1,024 patients used our services, which means that the pharmacy is providing services to an additional 49 patients in 2018, which further shows the need for intrathecal infusion services is rapidly growing. A pharmacy and nursing partnership simplifies the intrathecal infusion refill process for the practitioner and the patient.

The Projected Utilization Table in Attachment: Section B-Need C is noted. In that table it is also noted the applicant is projecting 5,334 procedures in Year One and 8,001 in Year Two of the proposed project. Please explain the methodology used to project the procedures. In addition, how did the applicant project overall 106,686 Tennessee patients would receive intrathecal and immunological infusion nursing services in Year One?

ANS is submitting a Revised Projected Utilization Table as provided in **Attachment 18** to replace the previously submitted Attachment: Section B-Need C. Section B, Need, Item F. ANS anticipates completing 304 visits in the first year of business. The projection is based on patients' use of pharmaceutical services in 2017. ANS anticipates that slightly more than ten-percent of the 985 patients (roughly 101 patients) will use our nursing services in Year 1. ANS projects ten-percent growth in Year 2, thus increasing the projected number of the number of patients receiving services to approximately 112. ANS anticipates that patients in Year 2 will require 5.5 visits on average. The methodology used to determine the average number of visits per patients in Year 1 (approximately 3 per patient) and Year 2 (approximately 5.5) takes into consideration the staggered/rolling referrals of patients in Year 1. For example, a patient referred to ANS in August of Year 1 will not receive the average number of infusion refills.

Is it possible to provide 5,334 procedures in Year One and 8,001 in Year Two in 95 counties with only 6 registered nurses?

ANS is submitting a Revised Projected Utilization Table (as provided in **Attachment 18)** to replace the previously submitted Attachment: Section B-Need C. Section B, Need, Item F. Also, based on the new projections, ANS projects 5 nurses (2.5 FTEs) will cover business needs in the first two years of operation.

17. Section B. Economic Feasibility Item A, Project Costs Chart

The Project Cost Chart total calculates to $47,936. If needed, please correct and submit a revised Project Cost Chart.

See **Attachment 28: Revised Project Cost Chart.** ANS is submitting a revised Project Cost Chart. The projected cost of the project is $48,936.

Please clarify how the applicant calculated a facility cost of $6,936 while the facility agreement appears to be month to month.

ANS calculated facility cost based on the sum of 12 months of rent expenses. ANS is entering into a one-year lease effective July 1, 2018 as shown in **Attachment 7: Lease and Renewal of Lease**

Your response is noted. However, please clarify if laptops, electronic record system, office equipment, portable electronic equipment, etc. has been accounted for in the Project Costs Chart.

Yes.

18. Section B. Economic Feasibility Item B Funding

It is noted the proposed project will be funded by cash reserves. Please provide documentation from the Chief Financial Officer of the organization providing funding for the project and latest audited financial statement of the organization.

See **Attachment 19: Financial Statements and Bank Letters. A guaranty agreement between Bond Pharmacy, Inc. dba Advanced Infusion Solutions and ANS is also included as an attachment.**

19. Section B. Economic Feasibility Item D Projected Data Chart

The Projected Data Chart for the total facility is noted. Please provide the following revisions and submit a revised Projected Data Chart labeled as pages 29 (R) and 30 (R). ANS is submitting revised projected data charts. See **Attachment 20: Revised Projected Data Charts for Nursing.**

- **Please provide the number of patients, visits, and hours for Year One and year Two.**
    - ANS projects providing services to 101 patients in Year 1. ANS approximates 304 visits/304 hours will be completed in Year 1. ANS projects providing services to 112 patients in Year 2. ANS approximates 616 visits/616 hours will be completed in Year 2.
- **Please itemize line D.6 Other Operating Expenses on page 30 of the application.**
    - Other Operating Expenses include mileage reimbursement, cell phones, office supplies, utilities and janitorial services. Other Operating Expenses for pharmacy's projected data chart also includes corporate overhead expenses.
- **Please explain the reason there is no provision for charity care or bad debt in the Projected Data Chart.**
    - See Revised Projected Data chart that includes charity care and bad debt. Since ANS is not a Medicare -certified agency, ANS is unable to participate in the Tenncare network. However, ANS is allocating funds that may be used to assist patients who would benefit from our home care services.
- **Please specify the type of revenue in line B 1-4 of the Projected Data Chart.**
    - The Revised Data Chart provides a designation for the type of revenue generated from the service line.

- **Please clarify is the Projected Data Chart is for total nursing or total pharmaceuticals.**
    - See Revised projected data charts. As requested, ANS is provided three data charts outlined below:

Please provide the following three Projected Data Charts: 1) Nursing Only, 2) Pharmaceuticals Only, and 3) Nursing and Pharmaceuticals Combined.

See **Attachment 21: Projected Data Charts for Nursing, Pharmaceuticals and Nursing/Pharmaceuticals.**

Please clarify where the cost of automobiles, cell phones, and mileage are accounted for in the Projected Data Chart.

Other Operating Expenses include mileage reimbursement, cell phones, office supplies, utilities and janitorial services.

20. Section B, Economic Feasibility, Item E.1

The chart on page 31 of the average gross charge, average deduction from operating revenue, and average net charge is noted. However, please provide by patient and visit. Please correct and submit a revised page 31.

See **Attachment 22: Revised Page 31, Section B, Economic Feasibility, Item E.1.**

21. Section B, Economic Feasibility, Item E.3

Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s). Please provide a narrative response and is necessary, use attachments as supporting documents.

See **Attachment 23: Fee Comparison – JAR Data.**

The fees charged by home health agencies offering similar or same services range from $138-$275[3]. Our projected fee of $175 falls within the range of services offered by similar or same home health agencies.

22. Section B, Economic Feasibility, Item F.1

Discuss how projected utilization rates will be sufficient to support the financial performance. Indicate when the project's financial breakeven is expected and demonstrate the availability of sufficient cash flow until financial viability is achieved. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For all projects,

[3] The JAR report indicates that Pentec Health's charge per visit is $275 for skilled nursing care. Pentec offers the same services ANS is proposing to provide.

recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For all projects, provide financial information for the corporation, partnership, or principal parties that will be a source of funding for the project.

The companies projected a profit in Year 2 as shown in the consolidated projected data chart. The companies anticipate to breakeven in the second quarter of 2020. See **Attachment 24: Financial Statements and Bank Letters.** AIS also serves as a guaranty of funds to ensure the project as shown in the attachment.

23. Section B, Economic Feasibility, Item F.3

The capitalization ratio of 47.3 is noted. Please indicate how the capitalization ratio was calculated.

The capitalization ratio of 47.3 is erroneous since new information is provided with the supplemental submission. Based on current information, the capitalization ratio is 159.4%. Capitalization was determined by using the following ratio: long-term debt/ (long term debt + total equity (net assets))) x 100. The calculations were completed by using the 2017 audited balance sheet.[4]

24. Section B, Economic Feasibility, Item H

The staffing table is noted. However, columns 1 and 2 are incorrectly completed and the Projected FTEs in Year One totals 3.1 rather than 6. Please complete the following table for both direct care and indirect care positions.

Please note that based on revised projected patients/visits/hours in the Year 1 and Year 2 of the project, ANS anticipates having five direct patient care positions, which equates to 2.5 full-time nurses in Year 1. Nurses typically have a workload of 35-40 patients. Therefore, five nurses will have a reasonable workload and ANS can hire nurses in more geographic areas in order to cover the state of Tennessee.

Position Classification	Existing FTEs (enter year)	Projected FTEs Year 1	Average Wage (Contractual Rate)	Area Wide/Statewide Average Wage
a) Direct Patient Care Positions				
Nursing-				
Registered Nurse	1	1	$32-$42	$27.27/hr
Registered Nurse	0.5	1	$32-$42	$27.27/hr.
Registered Nurse	0.1	0.1	$32-$42	$27.27/hr.
Registered Nurse	0.1	0.2	$32-$42	$27.27/hr.
Registered Nurse	0.1	0.1	$32-$42	$27.27/hr.
Total Direct Patient Care Positions	1.8	2.5		

[4] Please note that AIS and ANS are privately-held entities.

Pharmacy-				
Intake/ Cust Service	0.03	0.06	$14-$20	
RPH	0.06	0.12	$55-$70	
Pharm Tech	0.07	0.14	$22-$22	
Financial Services	0.2	0.4	$13-$20	
Total Direct Patient Care Positions	0.36	0.72		

b) Non-Patient Care Positions				
Nurse Manager	0.12	0.17		
Total Non-Patient Care Positions	0.12	0.17		
Total Employees *(A+B)*	2.28	3.39		
c) Contractual Staff		0		
Total Staff *(a+b+c)*	2.28	3.39		

Please clarify if registered nurses will have the Certified Registered Nurse Infusion (CRNI) Designation.

ANS encourages nurses to complete American Society for Pain Management Nursing (ASPMN) or Immunoglobin Certified Nurse (IgCN) or CRNI certifications, but certification is not required for employment. ANS currently employs several nurses who have the certifications noted above.

Please provide an overview of how home health infusion staff will be distributed in the 95 proposed county service area.

The patients will be assigned to nurses based on the geographical area. Nurses are field based and patients are assigned accordingly. ANS will target hiring employees located in Shelby, Davidson, Knox and Hamilton counties to ensure nurses' travel time to patients is within any time/distance requirements in Tennessee. Strategically hiring nurses in these areas should allow us to cover most of the rural counties in Tennessee as well.

If approved, please clarify if the applicant will subcontract any home health services associated with this application.

Our intent and plan is to use only ANS nurses to care for the specialty intrathecal infusion patients. ANS anticipates using ANS nurses for immunoglobulin care but may subcontract with other home health agencies if ANS is unable to provide the service.

ANS will meet the minimum staffing requirements that apply to licensed home health agencies in Tennessee. Nurses carry a patient assignment of 30-45 patients as a case load. ANS projects serving 101 patients in Year 1 with 5 nurses (full-time employees equal 2.5). This is based on patient acuity and geographic considerations. Nurses will be hired on a full-time, part-time or PRN basis dependent on the patient need. The company is willing to add staff members as needed.

25. Section B, Orderly Development, Item B.2

If approved, please specifically address the impact of the proposal on Pentec Health, CN1411-046A and Implanted Pump Management, LLC, CN1407-027A.

Pentec Health and Implanted Pump Management provide services that most closely match our company's service model. ANS does not anticipate a significant impact to the companies' businesses. ANS is using our pharmaceutical historical data to project where patient needs arise, and the data is based on practitioners that currently use AIS's pharmaceutical services. Therefore, it is highly likely that our business will derive from referrals made by physicians who currently use our pharmaceutical services.

As evidenced by our support letters, Tennessee practitioners believe additional home care services are needed in the State. There are currently a limited number of home health agencies offering intrathecal and immunologic services, and the entrance of new companies into this space creates more options for patients in Tennessee. Also, the market is not saturated by home health agencies providing the same services and is large enough for AIS, Pentec Health and Implanted Pump Management, LLC to be profitable in Tennessee.

26. Section B, Orderly Development, Item D

Please discuss ACHC accreditation and how this designation relates to the proposed project.

Home Health Agencies are required to have a process in place to assess and manage patient pain. In addition, agency regulations require physician supervision of patient care, including the plan of care (POC) developed for each patient and review by the MD at least once every 62 days or more often if severity of the patient's condition requires. Please describe how the applicant intends to comply with these patient care requirements as a condition of licensure in Tennessee.

ACHC accreditation indicates that an agency has successfully shown competence in the standards required by the accrediting body. ANS is accredited in infusion nursing which means ACHC considers ANS a quality provider of infusion therapy services. The accreditation is an overall quality measure showing ANS's commitment to

providing the highest level of service to its patients. Upon approval of this project, ANS will seek ACHC accreditation for the home health agency.

The Plan of Care will be sent to prescriber every 30 or 60 days (not to exceed 62 days) for review and signature. Patients receiving opioid therapies will be reviewed every 30 days; non-opioid patients will be reviewed every 60 days by the ordering physician. Patients are assessed for pain and/or spasticity with each skilled visit. Nursing notes and telemetry reports are provided to the physician/prescriber. Should a change in pain or spasticity assessment be assessed, the nurse will call the office to speak with practitioner and notify them verbally of the assessment
The pharmacist provides support and guidance for the nursing team regarding prescriptions. Prescription recommendations are discussed in internal telephonic or written care conferences and provided to physicians as needed.
Prescriber orders are required to provide any services requiring the administration of medication, treatment(s), and ongoing assessments.

27. Section B, Orderly Development, Item D.1 and D.2 -

It is noted the applicant has provisional licenses in Indiana and Kentucky. Please cite the reasons the licenses are provisional status.

ANS is awaiting a survey from the state regulatory agencies. The regulatory agencies must complete an on-site survey before ANS will receive a non-provisional license.

Please provide the latest State licensure survey for applicant related entities for Kansas, Arizona, Indiana, and Kentucky. If there are not deficiencies/findings, please provide documentation.

ANS does not have copies of state agencies' notes from the on-site survey. The state agencies issued our licenses since no deficiencies were noted during the Kansas and Arizone surveys.

It appears Bond Pharmacy, Inc. dba Advanced Infusion Solutions received warning letters from the U.S. Food and Drug Administration. If so, please provide copies of U.S. Food and Drug Administration inspection surveys and responses for Bond Pharmacy, Inc. dba Advanced Infusion Solutions for the latest three years.

See Attachment 25: **US. Food and Drug Administration ("FDA") – Bond Pharmacy Inc. dba Advanced Infusion Solutions**. FDA returned for re-inspection on November 6, 2017. Subsequently, FDA sent AIS a letter advising that the inspection is closed with no citations issued.

28. Project Completion Chart -

The Project Completion Chart is noted. However, the Issuance of Service is listed as June 22, 2018. Is this date correct? If not, please provide a replacement Project Completion Forecast Chart with the correct date.

See **Attachment 26: Revised Project Completion Forecast Chart** that shows an anticipated issuance of service date of June 22, 2019.

29. Proof of Publication

Please provide copies of the publication of intent of the required newspapers of general circulation in the proposed service area as listed in the letter of intent. Please submit a copy of the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit which is supplied by the newspaper as proof of the publication of the letter of intent that covers the 95 county proposed service area. Please insure the correct complete copy is paired with each appropriate affidavit.

Please complete the following chart:

Newspaper	Publication of Intent (Date)	Counties Covered

See **Attachment 27: Publication of Intent Chart & Newspaper Proof of Newspaper Publication.**

Publication of Intent was not published until the week of April 9-13 for the following counties: Grundy, Hardeman and Hickman.

Section A

Supplemental

Supplemental #2
June 15, 2018
11:27 A.M.

Supplemental Response:

2. Section A: Executive Summary (1) Description

A.—Supplemental Attachment 1

AIS Tennessee Pharmacy License.

Supplemental #2
June 15, 2018
11:27 A.M.

State of Tennessee
Department of Health

43437

TENNESSEE BOARD OF PHARMACY
PHARMACY
BOND PHARMACY, INC.
DBA ADVANCED INFUSION SOLUTION
623 HIGHLAND COLONY PKWY #100
RIDGELAND MS 39157

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000004688
EXPIRATION DATE: 07/31/2018

CONTROLLED SUBSTANCE REGISTRATION
STERILE COMPOUNDING

Rosemarie Ohr
DIRECTOR, HEALTH RELATED BOARDS

COMMISSIONER

DOF171

Supplemental Response:

2. Section A: Executive Summary (1) Description

E.—Supplemental Attachment 2

List of Home Health Agencies Providers Offering Similar Services.

Attachment 2 - List of HHA Providers Offering Infusion Services

Cumberland River Homecare (14024)
Suncrest Home Health (19324)
Suncrest Home Health (13032)
Suncrest Homes Health (21024)
Home Care Solutions (19544)
Coram CVS Specialty Infusion Services (19734)
Vanderbilt Affiliated Walgreens Services
Sun Home Health
Procare Home Health Services (30051)
Maxim Healthcare Services (33433)
Henry County Medical Center Home Health (40075)
NHC Homecare (60024)
Still Waters Home Health Agency (79526)
Coram CVS/Specialty Infusion Service (79556)
Pentec Health
Implanted Pump Management, LLC

Supplemental #2
June 15, 2018
11:27 A.M.

Supplemental Response:

2. Section A: Executive Summary (1) Description

H.—Supplemental Attachments 3 & 4

Charts-ICS Home Health Licenses; AIS Pharmacy License.

Attachment 3

Entity	State	Permit Type	Permit Number	Address	Medicaid/Medicare Certified?	Accreditation
Intrathecal Care Solutions, LLC dba Adanced Nursing Solutions	Arizona	Outpatient Treatment Center	OTC8490	1166 East Warner Rd #101 Q, Gilbert, AZ 8529	Yes- Medicare only	No
Intrathecal Care Solutions, LLC dba Adanced Nursing Solutions	Kentucky	Mobile Health Service License	License-(Pending) - 720437	Professional Towers, 4010 Dupont Circle, Louisville, KY 40207	No	No
Intrathecal Care Solutions, LLC	Kansas	Home Health Agency	A-046-189-2	12345 West 95th Street, Ste. 200, Office 12, Lenexa, KS 66215	No	No
Intrathecal Care Solutions, LLC dba Adanced Nursing Solutions	Indiana	Home Health Agency	(Provisional)-17-014235-2	4918 Temple Dr., Ste. D, Evansville, IN. 47715	No	No

Supplemental #2
June 15, 2018
11:27 A.M.

Attachment 4: Pharmacy Licenses

Entity	State	Permit Type	Permit Number	Address	Medicaid/Medicare Certified?	Accreditation
Advanced Infusion Solutions	AL	Pharmacy & C.S.	113398	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	AK	Pharmacy & C.S.	PHAO1381	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	AZ	Pharmacy & C.S.	Y005633	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	AZ	AZ Public Health License (?)	MED6958	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	AR	Pharmacy & C.S.	OS02197	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	CA	Pharmacy & C.S.	NRP 1331	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	CA	Sterile Compounding	NSC 100612	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	CO	Pharmacy & C.S.	OSP.0005874	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	CT	Pharmacy & C.S.	PCN.0002246	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	DE	Pharmacy	A9-0001252	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	DE	Controlled Substance	PH-0009321	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	FL	Pharmacy & C.S.	PH 28960	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	FL	Sterile Compounding	NSC 30	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	GA	Pharmacy & C.S.	PHNR000322	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	HI	Pharmacy	PMP 1016	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	HI	Controlled Substance	E11692	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	ID	Pharmacy & C.S.	21503MS	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	IL	Pharmacy	54.018232	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	IL	Controlled Substance	320.010557	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	IN	Pharmacy & C.S.	64001425A	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	IA	Pharmacy & C.S.	3949	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	KS	Pharmacy & C.S.	22-16453	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	KY	Pharmacy & C.S.	MS1637	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	LA	Pharmacy & C.S.	PHY.006705-NR	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	ME	Pharmacy & C.S.	MO40001605	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	MD	Pharmacy	P05975	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	MD	Controlled Substance	480547	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	MI	Pharmacy	5301010085	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	MI	Controlled Substance	5315059317	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	MN	Pharmacy & C.S.	264083	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	MS	Pharmacy (Ridgeland)	04274/2.0	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	MS	Controlled Substance (Ridgeland)	CS04274/2.0	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	MO	Pharmacy & C.S.	2013009831	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	MT	Pharmacy & C.S.	21569	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	NE	Pharmacy & C.S.	849	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	NV	Pharmacy & C.S.	PH02692	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	NH	Pharmacy & C.S.	NR0799	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	NJ	Pharmacy & C.S.	28RO00050700	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	NM	Pharmacy	PH00003531	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	NM	Controlled Substance	CS00218957	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	NY	Pharmacy & C.S.	030342	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes

Advanced Infusion Solutions	NC	Pharmacy & C.S.	11546	623 Highland Colony Pkwy,Ste.100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	ND	Pharmacy & C.S.	Phar926	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	OH	Pharmacy & C.S.	NRP.022033100	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	OK	Pharmacy & Parenteral	99-6622	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	OK	Controlled Substance	52305	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	OR	Pharmacy & C.S.	RP-0002618-CS	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	PA	Pharmacy & C.S.	NP000010	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	RI	Pharmacy & C.S.	PHN10588	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	SC	Pharmacy	15089	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	SC	Controlled Substance	13-15089	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	SD	Pharmacy & C.S.	400-0876	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	TN	Pharmacy, C.S. & Compounding Modifier	4688	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	TX	Pharmacy & C.S.	26830	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	UT	Pharmacy	8955795-1708	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	UT	Controlled Substance	8955795-8913	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	VT	Pharmacy & C.S.	036.0094512	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	VA	Pharmacy & C.S.	0214001307	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	WA	Pharmacy & C.S.	PHNR.FO.60449286	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	WV	Pharmacy	MO0560209	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	WV	Controlled Substance	MI0000719	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	WI	Pharmacy & C.S.	1140-43	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	WY	Pharmacy	NR-50599	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	WY	Controlled Substance	422AIS13	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	DC	Pharmacy	NRX0000407	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced Infusion Solutions	DC	Controlled Substance	NCP0000191	623 Highland Colony Pkwy,Ste. 100, Ridgeland, MS 39157	No	Yes
Advanced InfusionCare	MS	Pharmacy (Clinton)	14084/2.1	132 Fairmont Street, Suite B, Clinton MS 39056	No	Yes
Advanced InfusionCare	GA	Pharmacy	PHRE 008040	212 Northside Drive, Valdosta, GA 31602	No	Yes
Advanced InfusionCare	FL	Pharmacy	PH30725	212 Northside Drive, Valdosta, GA 31602	No	Yes
Advanced InfusionCare	AL	Pharmacy	114298	121 Oxmoor Blvd, Suite 100, Birmingham, AL 35209	No	Yes

Supplemental Response

2. Section A: Executive Summary (1) Description

I.-Supplemental Attachment 5

Call Center Training

Supplemental #2
June 15, 2018
11:27 A.M.

General Company Orientation (Company History, Mission, Vision, Purpose, Goals)
Organizational Management
Pharmacy Division (IT & Infusion)
Nursing Division (ANS - Home Refill, Clinic Refill, ACCS)
Sales Division (Regional & Account Managers, Territory Maps, Marketing, Partnering)
Corporate Compliance and Code of Conduct Training
JCAHO, ACHC, Annual Training, Certifications, and Quality Initiatives
Tour of facility (Call Center Offices, Administrative Offices, Pharmacy, Training rooms, Parking, Restrooms, Emergency Exits, Copy & Supply Room, Bulletin board, Break rooms, Conference rooms)
Department and Key Personnel Introductions
Introduction to ACCS Team
Introduction to Orientation Preceptors
HR and General Policies and Procedures
Compliance/Code of Conduct
Time and Attendance
Breaks & Lunch
Dress Code
Licensure Verification (Compact)
Payroll Strategies
Initial and Annual HR Competencies/OSHA/HIPPA
Evidence direct patient care staff has been offered Hep B. vaccination
TB Test/Health Screening per policy
ID Badges
Building access cards
Use of Surface Pro/Laptop/Desktop
Microsoft Outlook
Add Employee to Email Lists (ACCS internal, Nursing Telemetry Validation)
VPN Access
S Drive Access (Locates P&P, Nursing/ACCS Resources
CPR + Access and Overview
LYNX Access and Overview (Review pt info, HRF nursing notes, orders)
IS Support Contact (Phone and Email)

Supplemental #2
June 15, 2018
11:27 A.M.

Office/desk/work station
Phones, Computer, Fax, Efax, & Printers
Monitoring ACCS Mail, Email, Fax
Task completion
Calendar Scheduling
ACCS Team Meetings
Nurse/CSR Team Model
Nursing Connection Emails
Documentation (standards, timely and accurate submission)
SalesForce Training
POSITION INFORMATION
Review initial job assignments and training plans
Review job description and performance expectations and standards
Customer service and professional communication
Review job schedule and hours
Review After Hours requirements
Participation in special projects of interest
Quality Monitoring
Performance Reviews (3 months, 6 months, Annual)
Annual Standards and ongoing Nurse Training/Education/CEU
Rewards and Recognition Program
NURSE LICENSURE
Non-Compact State Licensure Planning (21 states)
CUE Requirements
Criminal Background Checks/Fingerprinting
Licensure Verification (NURSYS)
Transcripts
Passport Photos
Applications (Online & Mail)
Licensure Copies, Expiration Dates (Send to HR for tracking)
Renewal and CEU Requirements
ACCS POLICIES, PROCEDURES, SCRIPTS, FORMS
Review and Acknowledge understanding AIS General Nurse P&P (see list provided)
Review and Acknowledge understanding ACCS Scripts (see list provided)
Review and Acknowledge understanding ACCS Specific P&P (see list provided)
Review and Acknowledgement ACCS Forms (see list provided)
CLINICAL ORIENTATION
Pain Management Overview

Supplemental #2
June 15, 2018
11:27 A.M.

Disease states and patient management
Psychologic effects and Chronic Pain
Opioid safety and monitoring
Intrathecal (IT)- Targeted Drug Delivery Overview
IT Indications, Contraindications, Warnings, & Precautions
IT Trial and surgical procedure
IT Medication Overview, MOA, Adverse Effects, PDIs
PACC Guidelines
IT Emergency Procedures (Narcan, Baclofen, Alarms, When to notify Physician)
IT Patient Education (Expectations, Activity, Limitations, Medications AE/OD/WD, Refill Compliance)
MRI Conditional and Procedure
Pump Alarms
PTM/PTC
How to read Telemetry
Conducting Real Time Telemetry Validation with Home Refill Nurses
Flowonix Pump Review
Medtronic Pump Review
Codman Pump Review
Pump Programming/Titration and Refill Procedure; Understanding Home Refill Nursing Role
ACCS Call Frequency and Risk Evaluations
Patient Crisis - Suicidal Patient
Triage, management, and education for Non-IT related complaints
Nursing responsibilities and scope of practice
Communication with Prescriber/HCP
Clinical Support Resources within AIS (Natalie, Liz, Su, Koshy, Cindy, Leanna)
Medtronic My E-Learning Curriculum completion

Supplemental Response:

3. Section A: Executive Summary, Rationale for Approval (2) Economic Feasibility

Supplemental Attachment 6

Tennessee Providers Requesting Additional Home Care Service Agencies

CPS

COMPREHENSIVE PAIN SPECIALISTS

Tennessee Department of Health
710 James Robertson Pkwy
Nashville, TN 37243

May 30, 2018

Re: Additional Home Care Service Certificate of Need

Dear Sir or Madam,

As an advanced practice nurse in the state of Tennessee, I am writing in support of AIS HealthCare's request to provide home care services for patients with implanted pain pumps living in the great state of Tennessee. As you are most keenly aware, we are in the midst of combatting an opioid epidemic crisis, across this country and in Tennessee. One of the tools pain managers may use in assisting to manage pain and reduce opioid use is an implanted pain pump. Implanted pain pumps (intrathecal infusion therapy) require highly skilled practitioners and nurses to manage this therapy. In my experience, the home care services which are prevalent in TN have been unable to accept these patients due to the training and skills required by the nursing staff.

Allowing AIS HealthCare service option will improve access to appropriately and professionally skilled care for patients who need intrathecal infusion therapy services and have transportation and/or mobility limitations. Providing quality care services offered in the home increases safety and care for these patients. With more home care services, patients in these vulnerable situations do not have to worry about the potential logistical challenges associated with receiving their infusion refill in our office, as missing their scheduled refills may result in short- or long-term medical problems, emergency room visits, medical condition exacerbations, increased risk to the patient's overall safety and well-being, and ultimately device failure may occur requiring surgical intervention.

The intent of this home care service is to provide an improved quality of life and function for patients, home safety monitoring, and highly skilled nurses to complete these specialized procedures.

While highly efficacious, there are substantial complexities associated with intrathecal infusions. Patient pumps must be refilled in a timely manner by qualified clinicians as mentioned above to avoid unnecessary emergent transport by ambulance or costly and critical interventions. Further as alluded to above, the majority of home care agencies are not trained and qualified to perform these specialty intrathecal pump services and could lead to increased cost and adverse outcomes to this fragile population, which I have unfortunately witnessed in my patient population when poorly trained nursing care failed to accurately refill one of these devices. These pumps are highly specialized therapies which require extensive training and competencies to increase the patient safety and outcomes. AIS HealthCare thoroughly trains each and every one of their nurses with competency checks and multiple safety check points and algorithms. I heartily endorse their endeavors to provide this highly specialized and necessary therapy, and respectfully request your consideration of adding them to Tennessee's home care provider options.

Sincerely,

S. Trent, APRN

Sarah Trent, MSN, APRN-BC, APN #10907

Supplemental #2
June 15, 2018
11:27 A.M.

CPS
COMPREHENSIVE PAIN SPECIALISTS
776 WEATHERLY DRIVE, SUITE B, CLARKSVILLE, TN 37043 | P 931.919.4330 | F 931.919.4331 | WWW.CPSPAIN.COM

Dear Tennessee Department of Health,

I am writing to support an increased number of home care services for patients with implanted pain pumps or immunoglobin infusion needs. An important and necessary element for care of these chronic patients is the provision of highly trained home nursing services for patients in the state of Tennessee.

More home care service options will improve access to care for patients who need intrathecal or immunological infusion therapy services. Providing quality care services offered in the home increases access to care for these patients. Additionally, home care greatly benefits patients who do not live in close proximity of their doctor's office, who do not have their own source of transportation or who do not have access to public transportation. With more home care services, patients do not have to worry about the potential logistical challenges associated with receiving their infusion refill in our office. More importantly, it will likely decrease the safety risks caused for patients who are unable to make their refill appointments.

The intent is to provide an improved Quality of Life and function for patients, home safety monitoring, and highly skilled nurses to complete these specialized procedures.

While highly efficacious, there are substantial complexities associated with intrathecal infusions. Patient pumps must be refilled in a timely manner by qualified clinicians. to avoid, unnecessary emergent transport by ambulance or costly and critical interventions. The majority of home care agencies are not trained and qualified to perform these specialty intrathecal pump services and could lead to increased cost and adverse outcomes to this fragile population. These are highly specialized therapies which require extensive training and competencies to increase the patient safety and outcomes.

Access to more home care services for intrathecal and immunoglobulin infusion patients could increase their quality of life. Please consider adding more home care providers that offer this highly specialized and necessary therapy.

Sincerely,

Rebekah Pierce APRN

Rebekah Pierce APRN

CLS 8242014

Supplemental #2
June 15, 2018
11:27 A.M.

ADVANCED SPINE
OF HEALTHSTAR PHYSICIANS

DENNIS G. HARRIS, MD

May 30, 2018

Dear Tennessee Department of Health,

I am writing to support an increased number of home care services for patients with implanted pain pumps or immunoglobin infusion needs. An important and necessary element for care of these chronic patients is the provision of highly trained home nursing services for patients in the state of Tennessee.

More home care service options will improve access to care for patients who need intrathecal or immunological infusion therapy services. Providing quality care services offered in the home increases access to care for these patients. Additionally, home care greatly benefits patients who do not live in close proximity of their doctor's office, who do not have their own source of transportation or who do not have access to public transportation. With more home care services, patients do not have to worry about the potential logistical challenges associated with receiving their infusion refill in our office. More importantly, it will likely decrease the safety risks caused for patients who are unable to make their refill appointments.

The intent is to provide an improved Quality of Life and function for patients, home safety monitoring, and highly skilled nurses to complete these specialized procedures.

While highly efficacious, there are substantial complexities associated with intrathecal infusions. Patient pumps must be refilled in a timely manner by qualified clinicians. to avoid, unnecessary emergent transport by ambulance or costly and critical interventions. The majority of home care agencies are not trained and qualified to perform these specialty intrathecal pump services and could lead to increased cost and adverse outcomes to this fragile population. These are highly specialized therapies which require extensive training and competencies to increase the patient safety and outcomes.

Access to more home care services for intrathecal and immunoglobulin infusion patients could increase their quality of life. Please consider adding more home care providers that offer this highly specialized and necessary therapy.

Sincerely,

420 W. MORRIS BLVD., SUITE 130 • MORRISTOWN, TN 37813
☎ 423.581.3939 🖷 423.839.0550

June 15, 2018
11:27 A.M.

Attention: Michelle Parker

May 30, 2018

Dear Tennessee Department of Health,

I am writing to support an increased number of home care services for patients with implanted pain pumps or immunoglobin infusion needs. An important and necessary element for care of these chronic patients is the provision of highly trained home nursing services for patients in the state of Tennessee.

More home care service options will improve access to care for patients who need intrathecal or immunological infusion therapy services. Providing quality care services offered in the home increases access to care for these patients. Additionally, home care greatly benefits patients who do not live in close proximity of their doctor's office, who do not have their own source of transportation or who do not have access to public transportation. With more home care services, patients do not have to worry about the potential logistical challenges associated with receiving their infusion refill in our office. More importantly, it will likely decrease the safety risks caused for patients who are unable to make their refill appointments.

The intent is to provide an improved Quality of Life and function for patients, home safety monitoring, and highly skilled nurses to complete these specialized procedures.

While highly efficacious, there are substantial complexities associated with intrathecal infusions. Patient pumps must be refilled in a timely manner by qualified clinicians. to avoid, unnecessary emergent transport by ambulance or costly and critical interventions. The majority of home care agencies are not trained and qualified to perform these specialty intrathecal pump services and could lead to increased cost and adverse outcomes to this fragile population. These are highly specialized therapies which require extensive training and competencies to increase the patient safety and outcomes.

Access to more home care services for intrathecal and immunoglobulin infusion patients could increase their quality of life. Please consider adding more home care providers that offer this highly specialized and necessary therapy.

Sincerely,

Barbara Shaw, RN

Barbara Shaw, RN
East Tennessee Brain and Spine Center
701 Med Tech Parkway, Suite 300
Johnson City, TN 37604

Attention: Michelle Parker

May 30, 2018

Dear Tennessee Department of Health,

I am writing to support an increased number of home care services for patients with implanted pain pumps or immunoglobin infusion needs. An important and necessary element for care of these chronic patients is the provision of highly trained home nursing services for patients in the state of Tennessee.

More home care service options will improve access to care for patients who need intrathecal or immunological infusion therapy services. Providing quality care services offered in the home increases access to care for these patients. Additionally, home care greatly benefits patients who do not live in close proximity of their doctor's office, who do not have their own source of transportation or who do not have access to public transportation. With more home care services, patients do not have to worry about the potential logistical challenges associated with receiving their infusion refill in our office. More importantly, it will likely decrease the safety risks caused for patients who are unable to make their refill appointments.

The intent is to provide an improved Quality of Life and function for patients, home safety monitoring, and highly skilled nurses to complete these specialized procedures.

While highly efficacious, there are substantial complexities associated with intrathecal infusions. Patient pumps must be refilled in a timely manner by qualified clinicians. to avoid, unnecessary emergent transport by ambulance or costly and critical interventions. The majority of home care agencies are not trained and qualified to perform these specialty intrathecal pump services and could lead to increased cost and adverse outcomes to this fragile population. These are highly specialized therapies which require extensive training and competencies to increase the patient safety and outcomes.

Access to more home care services for intrathecal and immunoglobulin infusion patients could increase their quality of life. Please consider adding more home care providers that offer this highly specialized and necessary therapy.

Sincerely,

Barbara Shaw, RN

Barbara Shaw, RN
East Tennessee Brain and Spine Center
701 Med Tech Parkway, Suite 300
Johnson City, TN 37604

Supplemental #2
June 15, 2018
11:27 A.M.

PAIN MEDICINE ASSOCIATES, P.C.

William T. Williams, M.D.
Sameh A. Ward, M.D.
David Dahl, M.D.
Michael Wilkinson, M.D.
C. Marcus Cooper, Ph.D.
Kristina Bagley, F.N.P.
Holly Broadwater, F.N.P.
Cheryl Conrad, F.N.P.
Shannon Hollowell, F.N.P.
Benjamin A. Meeks, F.N.P.
John Powell, P.A.-C
Vickie Stufflestreet, L.P.N.-C
Tony Villanueva, P.T.

May 30, 2018

Tennessee Department of Health
710 James Robertson Pkwy
Nashville, TN 37243

Dear Tennessee Department of Health:

I am writing to support an increased number of home care services for patients with implanted pain pumps or immunoglobin infusion needs. An important and necessary element for care of these chronic patients is the provision of highly-trained home nursing services for patients in the state of Tennessee.

More home care service options will improve access to care for patients who need intrathecal or immunological infusion therapy services. Providing quality care services offered in the home increases access to care for these patients. Additionally, home care greatly benefits patients who do not live in close proximity to their doctor's office, who do not have their own source of transportation, or who do not have access to public transportation. With more home care services, patients do not have to worry about the potential logistical challenges associated with receiving their infusion refill in our office. More importantly, it will likely decrease the safety risks caused for patients who are unable to make their refill appointments. The intent is to provide an improved quality of life and function for patients, home safety monitoring, and highly-skilled nurses to complete these specialized procedures.

While highly efficacious, there are substantial complexities associated with intrathecal infusions. Patient pumps must be refilled in a timely manner by qualified clinicians to avoid unnecessary emergent transport by ambulance or costly and critical interventions. The majority of home care agencies are not trained and qualified to perform these specialty intrathecal pump services and could lead to increased cost and adverse outcomes to this fragile population. These are highly specialized therapies which require extensive training and competencies to increase the patient safety and outcomes.

Continued

101 MedTech Parkway, Suite 200
Johnson City, Tennessee 37604
Phone: (423) 232-6120
Fax: (423) 232-6125

2202 North John B. Dennis Hwy,
Suite 200
Kingsport, Tennessee 37660
Phone: (423) 392-8690
Fax: (423) 392-8695

240 Medical Park Blvd.,
Suite 1500
Bristol, Tennessee 37620
Phone: (423) 968-9313
Fax: (423) 968-9696

Supplemental #2
June 15, 2018
11:27 A.M.

Access to more home care services for intrathecal and immunoglobulin infusion patients could increase their quality of life. Please consider adding more home care providers that offer this highly specialized and necessary therapy.

Sincerely,

Sameh A. Ward, M.D.
Pain Medicine Associates, P.C.

Supplemental #2
June 15, 2018
11:27 A.M.

PAIN MEDICINE ASSOCIATES, P.C.

William T. Williams, M.D.
Sameh A. Ward, M.D.
David Dahl, M.D.
Michael Wilkinson, M.D.
C. Marcus Cooper, Ph.D.
Kristina Bagley, F.N.P.
Holly Broadwater, F.N.P.
Cheryl Conrad, F.N.P.
Shannon Hollowell, F.N.P.
Benjamin A. Meeks, F.N.P.
John Powell, P.A.-C
Vickie Stufflestreet, L.P.N.-C
Tony Villanueva, P.T.

May 30, 2018

Tennessee Department of Health
710 James Robertson Pkwy
Nashville, TN 37243

Dear Tennessee Department of Health:

I am writing to support an increased number of home care services for patients with implanted pain pumps or immunoglobin infusion needs. An important and necessary element for care of these chronic patients is the provision of highly-trained home nursing services for patients in the state of Tennessee.

More home care service options will improve access to care for patients who need intrathecal or immunological infusion therapy services. Providing quality care services offered in the home increases access to care for these patients. Additionally, home care greatly benefits patients who do not live in close proximity to their doctor's office, who do not have their own source of transportation, or who do not have access to public transportation. With more home care services, patients do not have to worry about the potential logistical challenges associated with receiving their infusion refill in our office. More importantly, it will likely decrease the safety risks caused for patients who are unable to make their refill appointments. The intent is to provide an improved quality of life and function for patients, home safety monitoring, and highly-skilled nurses to complete these specialized procedures.

While highly efficacious, there are substantial complexities associated with intrathecal infusions. Patient pumps must be refilled in a timely manner by qualified clinicians to avoid unnecessary emergent transport by ambulance or costly and critical interventions. The majority of home care agencies are not trained and qualified to perform these specialty intrathecal pump services and could lead to increased cost and adverse outcomes to this fragile population. These are highly specialized therapies which require extensive training and competencies to increase the patient safety and outcomes.

Continued

101 MedTech Parkway, Suite 200
Johnson City, Tennessee 37604
Phone: (423) 232-6120
Fax: (423) 232-6125

2202 North John B. Dennis Hwy,
Suite 200
Kingsport, Tennessee 37660
Phone: (423) 392-6680
Fax: (423) 392-6685

240 Medical Park Blvd.,
Suite 1500
Bristol, Tennessee 37620
Phone: (423) 968-9313
Fax: (423) 968-9696

Supplemental #2
June 15, 2018
11:27 A.M.

Access to more home care services for intrathecal and immunoglobulin infusion patients could increase their quality of life. Please consider adding more home care providers that offer this highly specialized and necessary therapy.

Sincerely,

W. Turney Williams, M.D.
Pain Medicine Associates, P.C.

Supplemental Response:

4. Section A, Project Details, Item 6.A. Legal Interest

Supplemental Attachment 7

Lease Renewal

Regus

Online Office Agreement

Agreement Date : September 7, 2017 Confirmation No : 8053009

Business Center Details

TN, Nashville - Highland Ridge II

Address: 555 Mariott Drive
Suite 315
Nashville
Tennessee
37214
United States of America

Sales Manager: Justin Lavery

Client Details

Company Name: Intrathecal Care Solutions / DBA Advanced Nursing Solutions

Contact Name: David Cheek

Address: 623 Highland Colony Parkway
Suite 100
Ridgeland
Mississippi
39157
United States of America

Phone: 6808704701

Email: pcarter@aispaincare.com

Office Payment Details (exc. tax and exc. services)

Office Number	Number of people	Price per Office
347	1	$ 578.00

Initial Payment :		
	First month's fee :	$ 578.00
	Service Retainer :	$ 1,156.00
	Total Initial Payment :	$ 1,734.00

Service Provision : Start Date October 1, 2017

Comments:

* Month-to-Month Agreement

Terms and Conditions

We are Regus Management Group, LLC, the "Provider". This Agreement incorporates our terms of business set out on attached Terms and Conditions, attached House Rules and Service Price Guide (where available) which you confirm you have read and understood. We both agree to comply with those terms and our obligations as set out in them. This agreement is binding from the agreement date and may not be terminated once it is made, except in accordance with its terms. Note that the Agreement does not come to an end automatically. See "Cancellation" section of your terms and conditions

AGREEMENT TO ARBITRATE; CLASS ACTION WAIVER: Any dispute or claim relating in any way to this agreement shall be resolved by binding arbitration administered by the American Arbitration Association in accord with its Commercial Arbitration Rules (available at www.adr.org), except that you or the Provider may assert claims in small claims court and the Client and the Provider may pursue court actions to remove you, or prevent your removal, from the Center if you do not leave when this agreement terminates. The arbitrator shall have exclusive authority to resolve any dispute relating to the interpretation, applicability, enforceability, or formation of this agreement. The arbitrator shall not conduct arbitration as a class or representative action. The Client and the Provider acknowledge that this agreement is a transaction in interstate commerce governed by the Federal Arbitration Act. The Client and the Provider agree to waive any right to pursue any dispute relating to this agreement in any class, private attorney general, or other representative action.

☑ I accept the terms and conditions

Download the terms and conditions

Download the house rules

☐ We and our preferred partners would like to keep you informed of the latest product news, special offers and other marketing information. If you would like to receive this information then select this box.

Confirm by typing your name in the box below

Name : David Cheek on behalf of Intrathecal Care Solutions / DBA Advanced Nursing Solutions

Signed on
September 12, 2017

I confirm these details are correct to the best of my knowledge

This website is secure. Your personal details are protected at all times.

Print Agreement

Regus

1. This Agreement

1.1 Nature of this agreement: This agreement is the commercial equivalent of an agreement for accommodation(s) in a hotel. The whole of the Center remains in the Provider's possession and control. THE CLIENT ACCEPTS THAT THIS AGREEMENT CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE OR OTHER REAL PROPERTY INTEREST IN THE CLIENT'S FAVOUR WITH RESPECT TO THE ACCOMMODATION(S). The Provider is giving the Client the right to share with the Provider the use of the Center on these terms and conditions, as supplemented by the House Rules, so that the Provider can provide the services to the Client. This Agreement is personal to the Client and cannot be transferred to anyone else without prior consent from the Provider unless such transfer is required by law. The Provider will not unreasonably withhold its consent to assignment to a parent, subsidiary or affiliate of Client provided that Client and assignee execute the Provider's form of Assignment of License Agreement which will require assignee to assume all Client obligations and will not release the Client. This agreement is composed of the front page describing the accommodation(s), the present terms and conditions, the House Rules and the Service Price Guide (where available).

1.2 Comply with House Rules: The Client must comply with any House Rules which the Provider imposes generally on users of the Center. The House Rules vary from country to country and from Center to Center and these can be requested locally.

1.3 AUTOMATIC RENEWAL: THIS AGREEMENT LASTS FOR THE PERIOD STATED IN IT AND **THEN WILL BE EXTENDED AUTOMATICALLY FOR SUCCESSIVE PERIODS EQUAL TO THE CURRENT TERM BUT NO LESS THAN 3 MONTHS** (UNLESS LEGAL RENEWAL TERM LIMITS APPLY) UNTIL TERMINATED BY THE CLIENT OR BY THE PROVIDER PERSUANT TO SECTION 1.4. UNTIL BROUGHT TO AN END BY THE CLIENT OR BY THE PROVIDER. ALL PERIODS SHALL RUN TO THE LAST DAY OF THE MONTH IN WHICH THEY WOULD OTHERWISE EXPIRE. THE FEES ON ANY RENEWAL WILL BE AT THE THEN PREVAILING MARKET RATE. THIS CLAUSE DOES NOT APPLY TO MONTH TO MONTH AGREEMENTS.

1.4 **CANCELLATION:** EITHER THE PROVIDER OR THE CLIENT CAN TERMINATE THIS AGREEMENT AT THE END DATE STATED IN IT, OR AT THE END OF ANY EXTENSION OR RENEWAL PERIOD, BY GIVING AT LEAST THREE MONTHS WRITTEN NOTICE TO THE OTHER. HOWEVER, IF THIS AGREEMENT, EXTENSION OR RENEWAL IS FOR THREE MONTHS OR LESS AND EITHER THE PROVIDER OR THE CLIENT WISHES TO TERMINATE IT, THE NOTICE PERIOD IS TWO MONTHS IF THIS AGREEMENT, EXTENSION OR RENEWAL IS FOR TWO MONTHS OR LESS, NOTICE MUST BE GIVEN WITHIN ONE WEEK OF THE START DATE OF THE CURRENT TERM.IF THE CLIENT IS ON A MONTH TO MONTH AGREEMENT EITHER PARTY MAY TERMINATE THIS AGREEMENT BY GIVING NO LESS THAN ONE MONTHS' NOTICE TO THE OTHER (EFFECTIVE FROM THE START OF ANY CALENDAR MONTH).

1.5 Ending this agreement immediately: To the maximum extent permitted by applicable law, the Provider may put an end to this agreement immediately by giving the Client notice and without need to follow any additional procedure if (a) the Client becomes insolvent, bankrupt, goes into liquidation or becomes unable to pay its debts as they fall due, or (b) the Client is in breach of one of its obligations which cannot be put right or which the Provider have given the Client notice to put right and which the Client has failed to put right within fourteen (14) days of that notice, or (c) its conduct, or that of someone at the Center with its permission or invitation, is incompatible with ordinary office use and (i) such conduct is repeated despite the Client having been given a warning or (ii) such conduct is material enough (in the Provider's opinion) to warrant immediate termination.

If the Provider puts an end to this agreement for any of these reasons it does not put an end to any outstanding obligations, including additional services used, requested or required under the agreement and the monthly office fee for the remainder of the period for which this agreement would have lasted if the Provider had not ended it.

1.6 If the Center is no longer available: In the event that the Provider is permanently unable to provide the services and accommodation(s) at the Center stated in this agreement then this agreement will end and the Client will only have to pay monthly office fees up to the date it ends and for the additional services the Client has used. The Provider will try to find suitable alternative accommodation(s) for the Client at another Provider Center.

1.7 When this agreement ends the Client is to vacate the accommodation(s) immediately, leaving the accommodation(s) in the same condition as it was when the Client took it. Upon the Client's departure or if the Client, at its option, chooses to relocate to different rooms within the Center, the Provider will charge an Office Restoration Service fee to cover normal cleaning and testing and to return the accommodation(s) to its original state. This fee will differ by country and is listed in the House Rules. The Provider reserves the right to charge additional reasonable fees for any repairs needed above and beyond normal wear and tear. If the Client leaves any property in the Center the Provider may dispose of it at the Client's cost in any way the Provider chooses without owing the Client any responsibility for it or any proceeds of sale. If the Client continues to use the accommodation(s) when this agreement has ended the Client is responsible for any loss, claim or liability the Provider incurs as a result of the Client's failure to vacate on time. The Provider may, at its discretion, permit the Client an extension subject to a surcharge on the monthly office fee.

1.8 Employees: While this agreement is in force and for a period of six months after it ends, neither the Provider nor the Client may knowingly solicit or offer employment to any of the other's staff employed in the Center. This obligation applies to any employee employed at the Center up to that employee's termination of employment, and for three months thereafter. It is stipulated that the breaching party shall pay the non-breaching party the equivalent of six months' salary for any employee concerned. Nothing in this clause shall prevent either party from employing an individual who responds in good faith and independently to an advertisement which is made to the public at large.

1.9 Notices: All formal notices must be in writing, which may include by email, to the address first written above.

1.10 Confidentiality: The terms of this agreement are confidential. Neither the Provider nor the Client must disclose them without the other's consent unless required to do so by law or an official authority. This obligation continues for a period of 3 years after this agreement ends.

1.11 Applicable law: This agreement is interpreted and enforced in accordance with the law of the place where the relevant Center is located. All dispute resolution proceedings will be conducted in the country, state or province where the Center is located. If any provision of these terms and conditions is held void or unenforceable under the applicable law, the other provisions shall remain in force. In the case of Japan all agreements will be interpreted and enforced by the Tokyo District Court, and in the case of France, any dispute regarding this agreement will be settled by the relevant courts of the Paris jurisdiction.

2. Services and Obligations

2.1 Office accommodation(s): The Provider is to provide the number of serviced office accommodation(s) for which the Client has agreed to pay in the Center stated in this agreement. This agreement lists the accommodation(s) the Provider has initially allocated for the Client's use. The Client will have a non-exclusive right to the rooms allocated to it. Occasionally the Provider may need to allocate different accommodation(s), but these accommodation(s) will be of reasonably equivalent size and the Provider will notify the Client with respect to such different accommodation(s) in advance.

2.2 Office Services: The Provider is to provide during normal opening hours the services, if requested, described in the relevant service description (which is available on request). If the Provider decides that a request for any particular service is excessive, it reserves the right to charge an additional fee.

2.3 THE PROVIDER'S IT: WHILST THE PROVIDER HAS INTERNET SECURITY PROTOCOLS, THE PROVIDER DOES NOT MAKE ANY REPRESENTATIONS AS TO THE SECURITY OF THE PROVIDER'S NETWORK (OR THE INTERNET) OR OF ANY INFORMATION THAT THE CLIENT PLACES ON IT. The Client should adopt whatever security measures (such as encryption) it believes are appropriate to its circumstances. The Provider cannot guarantee that a particular degree of availability will be attained in connection with the Client's use of the Provider's network (or the Internet). The Client's sole and exclusive remedy shall be the remedy of such failure by the Provider within a reasonable time after written notice.

3. Providing the Services

3.1 Access to the accommodation(s): The Provider may need to enter the Client's accommodation(s) and may do so at any time. However, unless there is an emergency or the Client has given notice to terminate, the Provider will attempt to notify the Client verbally or electronically in advance when the Provider needs access to carry out testing, repair or works other than routine inspection, cleaning and maintenance. The Provider will also endeavor to respect reasonable

security procedures to protect the confidentiality of the Client's business.

3.2 Availability at the start of this agreement: If for any reason the Provider cannot provide the accommodation(s) stated in this agreement by the date when this agreement is due to start it has no liability to the Client for any loss or damages but the Client may cancel this agreement without penalty. The Provider will not charge the Client the monthly office fee for accommodation(s) the Client cannot use until it becomes available. The Provider may delay the start date of this agreement provided it provides to the Client alternative accommodation(s) that shall be at least of equivalent size to the accommodation(s) stated in this agreement.

4. Accommodation(s)

4.1 The Client must not alter any part of its accommodation and must take good care of all parts of the Center, its equipment, fixtures, fittings and furnishings which the Client uses. The Client is liable for any damage caused by it or those in the Center with the Client's permission or at the Client's invitation whether express or implied, including but not limited to all employees, contractors, agents or other persons present on the premises.

4.2 Office equipment: The Client must not install any cabling, IT or telecom connections without the Provider's consent, which the Provider may refuse at its absolute discretion.

As a condition to the Provider's consent, the Client must permit the Provider to oversee any installations (for example IT or electrical systems) and to verify that such installations do not interfere with the use of the accommodation(s) by other Clients or the Provider or any landlord of the building.

4.3 Insurance: It is the Client's responsibility to arrange insurance for its own property which it brings in to the Center and for its own liability to its employees and to third parties. The Provider strongly recommends that the Client put such insurance in place.

5. Use

5.1 The Client must only use the accommodation(s) for office purposes. Office use of a "retail" or "medical" nature, involving frequent visits by members of the public, is not permitted.

5.2 The Client must not carry on a business that competes with the Provider's business of providing serviced office accommodation(s) or its ancillary services.

5.3 The Client's name and address: The Client may only carry on that business in its name or some other name that the Provider previously agrees.

5.4 Use of the Center Address: The Client may use the Center address as its business address. Any other uses are prohibited without the Provider's prior written consent.

6. Compliance

6.1 Comply with the law: The Client and the Provider must comply with all relevant laws and regulations in the conduct of its business in relation to this agreement. The Client must do nothing illegal in connection with its use of the Business Center. The Client must not do anything that may interfere with the use of the Center by the Provider or by others, (including but not limited to political campaigning or immoral activity), cause any nuisance or annoyance, increase the insurance premiums the Provider has to pay, or cause loss or damage to the Provider (including damage to reputation) or to the owner of any interest in the building which contains the Center the Client is using. Both the Client and the Provider shall comply at all times with all relevant anti-bribery and anti-corruption laws. The Provider confirms that in providing the services it has not employed or used any labor in contravention of the requirements of any anti-slavery laws.

6.2 If the Provider has been advised by any government authority or other legislative body that it has reasonable suspicion that the Client is conducting criminal activities from the Center then the Provider shall be entitled to terminate this agreement with immediate effect.

6.3 The Client acknowledges that (a) the terms of this clause are a material inducement in the Provider's execution of this agreement and (b) any violation by the Client of this clause shall constitute a material default by the Client hereunder, entitling the Provider to terminate this agreement, without further notice or procedure.

6.4 The Provider may collect and process personal data from and of the Client to administer contractual relationship, ensure compliance with applicable laws and regulations, and enable the Provider to provide its services and to manage its business. The Client acknowledges and accepts that such personal data may be transferred or made accessible to all entities of the Provider's group, wherever located, for the purposes of providing the services herein.

7. The Provider's Liability

7.1. The extent of the Provider's liability: To the maximum extent permitted by applicable law, the Provider is not liable to the Client in respect of any loss or damage the Client suffers in connection with this agreement, with the services or with the Client's accommodation(s) unless the Provider has acted deliberately or negligently in causing that loss or damage. the Provider is not liable for any loss as a result of the Provider's failure to provide a service as a result of mechanical breakdown, strike, termination of the Provider's interest in the building containing the Center or otherwise unless the Provider does so deliberately or is negligent. In no event shall the Provider be liable for any loss or damage until the Client provides the Provider written notice and gives the Provider a reasonable time to put it right. If the Provider is liable for failing to provide the Client with any service under this agreement then subject to the exclusions and limits set out immediately below the Provider will pay any actual and reasonable expenses the Client has incurred in obtaining that service from an alternative source. If the Client believes the Provider has failed to deliver a service consistent with these terms and conditions the Client shall provide the Provider written notice of such failure and give the Provider a reasonable period to put it right.

7.2. EXCLUSION OF CONSEQUENTIAL LOSSES, ETC.: THE PROVIDER WILL NOT IN ANY CIRCUMSTANCES HAVE ANY LIABILITY FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA, THIRD PARTY CLAIMS OR ANY CONSEQUENTIAL LOSS UNLESS THE PROVIDER OTHERWISE AGREES IN WRITING. THE PROVIDER STRONGLY ADVISES THE CLIENT TO INSURE AGAINST ALL SUCH POTENTIAL LOSS, DAMAGE, EXPENSE OR LIABILITY.

7.3. Financial limits to the Provider's liability: In all cases, the Provider's liability to the Client is subject to the following limits:

- Without limit for personal injury or death;
- Up to a maximum of £1 million / USD$2 million / €1.3 million (or local equivalent) for any one event or series of connected events for damage to the Client's personal property;
- Up to a maximum equal to 125% of the total fees paid between the date the Client moved into its accommodation(s) and the date on which the claim in question arises or £50,000 / USD$100,000 / €66,000 (or local equivalent) whichever is the higher, in respect of any other loss or damage.

8. Fees

8.1 Taxes and duty charges: The Client agrees to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which it is required to pay to any governmental authority (and, at the Provider's request, will provide to the Provider evidence of such payment) and (ii) any taxes paid by the Provider to any governmental authority that are attributable to the accommodation(s), including, without limitation, any gross receipts, rent and occupancy taxes, tangible personal property taxes, stamp tax or other documentary taxes and fees.

8.2 Service Retainer/Deposit: The Client will be required to pay a service retainer/deposit equivalent to two months' of the monthly office fee (plus VAT/Tax where applicable) upon entering into this agreement unless a different amount is specified on the front of this agreement. This will be held by the Provider without generating interest as security for performance of all the Client's obligations under this agreement. The service retainer/deposit or any balance will be returned to the Client when the Client has settled its account which includes deducting outstanding fees and other costs due to the Provider.

8.3 The Provider may require the Client to pay an increased retainer if outstanding fees exceed the service retainer/deposit held and/or the Client frequently fails to pay the Provider when due.

8.4 Payment: The Provider is continually striving to reduce its environmental impact and supports its clients in doing the same. Therefore the Provider will send all invoices electronically (where allowed by law) and the Client will make payments via an automated method such as Direct Debit or Credit Card, wherever local banking systems permit unless another form of payment is offered to the Client as a qualified and current Key Account. All amounts payable by the

Client under this agreement may be assigned to other members of the Provider's group.

8.5 Late payment: If the Client does not pay fees when due, a fee will be charged on all overdue balances. This fee will differ by country and is listed in the House Rules. If the Client disputes any part of an invoice the Client must pay the amount not in dispute by the due date or be subject to late fees. The Provider also reserves the right to withhold services (including for the avoidance of doubt, denying the Client access to its accommodation(s)) while there are any outstanding fees and/or interest or the Client is in breach of this agreement.

8.6 Insufficient Funds: The Client will pay a fee for any returned check or any other declined payments due to insufficient funds. This fee will differ by country and is listed in the House Rules.

8.7 If this agreement is for a term of more than 12 months, the Provider will increase the monthly office fee on each anniversary of the start date. This increase will be by the local Consumer Price Index or such other broadly equivalent index where a consumer price index is not available locally. If there is a negative index rate, prices will not be decreased. Renewals are calculated separately from annual indexation increases. Month to Month agreements will use the above stated index or the current month to month office price, whichever is the greater.

8.8 Standard services: The monthly office fee and any recurring services requested by the Client are payable monthly in advance. Unless otherwise agreed in writing, these recurring services will be provided by the Provider at the specified rates for the duration of this Agreement (including any renewal). Specific due dates will differ by country and are listed in the House Rules. Where a daily rate applies, the charge for any such month will be 30 times the daily fee. For a period of less than a month the fee will be applied on a daily basis.

8.9 Pay-as-you-use and Additional Variable Services: Fees for pay-as-you-use services, plus applicable taxes, in accordance with the Provider's published rates which may change from time to time, are invoiced in arrears and payable the month following the calendar month in which the additional services were provided. Specific due dates will differ by country and are listed in the House Rules.

8.10 Discounts, Promotions and Offers: If the Client benefited from a special discount, promotion or offer, the Provider may discontinue that discount, promotion or offer without notice if the Client breaches these terms and conditions or becomes past due on two or more occasions.

Regus HQ

Supplemental #2
June 15, 2018
11:27 A.M.

Renewal Agreement

Client Details			
Company Name:	Intrathecal Care Solutions/DBA Adv. Nursing Solution	**Center:**	3260- Nashville, Highland Ridge
Contact Name:	Pamela Carter	**Reference No.:**	8513813

Office Details (excluding VAT/Tax and Services)

Office Number	Monthly Office Price		
	12 Month Option A	_____ Months Option B	_____ Months Option C
347	539.00		
Total per Month	539.00		

USD

Start Date of Renewal:	July 1, 2018

Comments:

12 months End date will be June 30th, 2019

Please place an "**X**" in the shaded box next to your preferred option:

Option A: I agree ☐

Option B: I agree ☐

Option C: I agree ☐

I do not wish to renew ☐

Name (printed):

Title (printed):

Date:

SIGNED on your behalf (Client)

Name (printed):

Title (printed):

Date:

SIGNED on our behalf

Terms & Conditions

Supplemental #2

June 15, 2018
11:27 A.M.

1. This Agreement

1.1 Nature of this agreement: This agreement is the commercial equivalent of an agreement for accommodation(s) in a hotel. The whole of the Center remains in the Provider's possession and control. THE CLIENT ACCEPTS THAT THIS AGREEMENT CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE OR OTHER REAL PROPERTY INTEREST IN THE CLIENT'S FAVOUR WITH RESPECT TO THE ACCOMMODATION(S). The Provider is giving the Client the right to share with the Provider the use of the Center on these terms and conditions, as supplemented by the House Rules, so that the Provider can provide the services to the Client. This Agreement is personal to the Client and cannot be transferred to anyone else without prior consent from the Provider unless such transfer is required by law. The Provider will not unreasonably withhold its consent to assignment to a parent, subsidiary or affiliate of Client provided that Client and assignee execute the Provider's form of Assignment of License Agreement which will require assignee to assume all Client obligations and will not release the Client. This agreement is composed of the front page describing the accommodation(s), the present terms and conditions, the House Rules and the Service Price Guide (where available).

1.2 Comply with House Rules: The Client must comply with any House Rules which the Provider imposes generally on users of the Center. The House Rules vary from country to country and from Center to Center and these can be requested locally.

1.3 AUTOMATIC RENEWAL: THIS AGREEMENT LASTS FOR THE PERIOD STATED IN IT AND **THEN WILL BE EXTENDED AUTOMATICALLY FOR SUCCESSIVE PERIODS EQUAL TO THE CURRENT TERM BUT NO LESS THAN 3 MONTHS** (UNLESS LEGAL RENEWAL TERM LIMITS APPLY) UNTIL TERMINATED BY THE CLIENT OR BY THE PROVIDER PERSUANT TO SECTION 1.4. UNTIL BROUGHT TO AN END BY THE CLIENT OR BY THE PROVIDER. ALL PERIODS SHALL RUN TO THE LAST DAY OF THE MONTH IN WHICH THEY WOULD OTHERWISE EXPIRE. THE FEES ON ANY RENEWAL WILL BE AT THE THEN PREVAILING MARKET RATE. THIS CLAUSE DOES NOT APPLY TO MONTH TO MONTH AGREEMENTS.

1.4 **CANCELLATION:** EITHER THE PROVIDER OR THE CLIENT CAN TERMINATE THIS AGREEMENT AT THE END DATE STATED IN IT, OR AT THE END OF ANY EXTENSION OR RENEWAL PERIOD, BY GIVING AT LEAST THREE MONTHS WRITTEN NOTICE TO THE OTHER. HOWEVER, IF THIS AGREEMENT, EXTENSION OR RENEWAL IS FOR THREE MONTHS OR LESS AND EITHER THE PROVIDER OR THE CLIENT WISHES TO TERMINATE IT, THE NOTICE PERIOD IS TWO MONTHS OR (IF TWO MONTHS OR SHORTER) ONE WEEK LESS THAN THE PERIOD STATED IN THIS AGREEMENT. IF THE CLIENT IS ON A MONTH TO MONTH AGREEMENT EITHER PARTY MAY TERMINATE THIS AGREEMENT BY GIVING NO LESS THAN ONE MONTHS' NOTICE TO THE OTHER (EFFECTIVE FROM THE START OF ANY CALENDAR MONTH).

1.5 Ending this agreement immediately: To the maximum extent permitted by applicable law, the Provider may put an end to this agreement immediately by giving the Client notice and without need to follow any additional procedure if (a) the Client becomes insolvent, bankrupt, goes into liquidation or becomes unable to pay its debts as they fall due, or (b) the Client is in breach of one of its obligations which cannot be put right or which the Provider have given the Client notice to put right and which the Client has failed to put right within fourteen (14) days of that notice, or (c) its conduct, or that of someone at the Center with its permission or invitation, is incompatible with ordinary office use and (i) such conduct is repeated despite the Client having been given a warning or (ii) such conduct is material enough (in the Provider's opinion) to warrant immediate termination.

If the Provider puts an end to this agreement for any of these reasons it does not put an end to any outstanding obligations, including additional services used, requested or required under the agreement and the monthly office fee for the remainder of the period for which this agreement would have lasted if the Provider had not ended it.

1.6 If the Center is no longer available: In the event that the Provider is permanently unable to provide the services and accommodation(s) at the Center stated in this agreement then this agreement will end and the Client will only have to pay monthly office fees up to the date it ends and for the additional services the Client has used. The Provider will try to find suitable alternative accommodation(s) for the Client at another Provider Center.

1.7 When this agreement ends the Client is to vacate the accommodation(s) immediately, leaving the accommodation(s) in the same condition as it was when the Client took it. Upon the Client's departure or if the Client, at its option, chooses to relocate to different rooms within the Center, the Provider will charge an Office Restoration Service fee to cover normal cleaning and testing and to return the accommodation(s) to its original state. This fee will differ by country and is listed in the House Rules. The Provider reserves the right to charge additional reasonable fees for any work needed above and beyond normal wear and tear. If the Client leaves any property in the Center the Provider may dispose of it at the Client's cost in any way the Provider chooses without owing the Client any responsibility for it or any proceeds of sale. If the Client continues to use the accommodation(s) when this agreement has ended the Client is responsible for any loss, claim or liability the Provider incurs as a result of the Client's failure to vacate on time. The Provider may, at its discretion, permit the Client an extension subject to a surcharge on the monthly office fee.

1.8 Employees: While this agreement is in force and for a period of six months after it ends, neither the Provider nor the Client may knowingly solicit or offer employment to any of the other's staff employed in the Center. This obligation applies to any employee employed at the Center up to that employee's termination of employment, and for three months thereafter. It is stipulated that the breaching party shall pay the non-breaching party the equivalent of six months' salary for any employee concerned. Nothing in this clause shall prevent either party from employing an individual who responds in good faith and independently to an advertisement which is made to the public at large.

1.9 Notices: All formal notices must be in writing, which may include by email, to the address first written above.

1.10 Confidentiality: The terms of this agreement are confidential. Neither the Provider nor the Client must disclose them without the other's consent unless required to do so by law or an official authority. This obligation continues for a period of 3 years after this agreement ends.

1.11 Applicable law: This agreement is interpreted and enforced in accordance with the law of the place where the relevant Center is located. All dispute resolution proceedings will be conducted in the country, state or province where the Center is located. If any provision of these terms and conditions is held void or unenforceable under the applicable law, the other provisions shall remain in force. In the case of Japan all agreements will be interpreted and enforced by the Tokyo District Court, and in the case of France, any dispute regarding this agreement will be settled by the relevant courts of the Paris jurisdiction.

2. Services and Obligations

2.1 Office accommodation(s): The Provider is to provide the number of serviced office accommodation(s) for which the Client has agreed to pay in the Center stated in this agreement. This agreement lists the accommodation(s) the Provider has initially allocated for the Client's use. The Client will have a non-exclusive right to the rooms allocated to it. Occasionally the Provider may need to allocate different accommodation(s), but these accommodation(s) will be of reasonably equivalent size and the Provider will notify the Client with respect to such different accommodation(s) in advance.

2.2 Office Services: The Provider is to provide during normal opening hours the services, if requested, described in the relevant service description (which is available on request). If the Provider decides that a request for any particular service is excessive, it reserves the right to charge an additional fee.

2.3 THE PROVIDER'S IT: WHILST THE PROVIDER HAS INTERNET SECURITY PROTOCOLS, THE PROVIDER DOES NOT MAKE ANY REPRESENTATIONS AS TO THE SECURITY OF THE PROVIDER'S NETWORK (OR THE INTERNET) OR OF ANY INFORMATION THAT THE CLIENT PLACES ON IT. The Client should adopt whatever security measures (such as encryption) it believes are appropriate to its circumstances. The Provider cannot guarantee that a particular degree of availability will be attained in connection with the Client's use of the Provider's network (or the Internet). The Client's sole and exclusive remedy shall be the remedy of such failure by the Provider within a reasonable time after written notice.

3. Providing the Services

3.1 Access to the accommodation(s): The Provider may need to enter the Client's accommodation(s) and may do so at any time. However, unless there is an emergency or the Client has given notice to terminate, the Provider will attempt to notify the Client verbally or electronically in advance when the Provider needs access to carry out testing, repair or works other than routine inspection, cleaning and maintenance. The Provider will also endeavor to respect reasonable

security procedures to protect the confidentiality of the Client's business.

3.2 Availability at the start of this agreement: If for any reason the Provider cannot provide the accommodation(s) stated in this agreement by the date when this agreement is due to start it has no liability to the Client for any loss or damages but the Client may cancel this agreement without penalty. The Provider will not charge the Client the monthly office fee for accommodation(s) the Client cannot use until it becomes available. The Provider may delay the start date of this agreement provided it provides to the Client alternative accommodation(s) that shall be at least of equivalent size to the accommodation(s) stated in this agreement.

4. Accommodation(s)

4.1 The Client must not alter any part of its accommodation and must take good care of all parts of the Center, its equipment, fixtures, fittings and furnishings which the Client uses. The Client is liable for any damage caused by it or those in the Center with the Client's permission or at the Client's invitation whether express or implied, including but not limited to all employees, contractors, agents or other persons present on the premises.

4.2 Office equipment: The Client must not install any cabling, IT or telecom connections without the Provider's consent, which the Provider may refuse at its absolute discretion.

As a condition to the Provider's consent, the Client must permit the Provider to oversee any installations (for example IT or electrical systems) and to verify that such installations do not interfere with the use of the accommodation(s) by other Clients or the Provider or any landlord of the building.

4.3 Insurance: It is the Client's responsibility to arrange insurance for its own property which it brings in to the Center and for its own liability to its employees and to third parties. The Provider strongly recommends that the Client put such insurance in place.

5. Use

5.1 The Client must only use the accommodation(s) for office purposes. Office use of a "retail" or "medical" nature, involving frequent visits by members of the public, is not permitted.

5.2 The Client must not carry on a business that competes with the Provider's business of providing serviced office accommodation(s) or its ancillary services.

5.3 The Client's name and address: The Client may only carry on that business in its name or some other name that the Provider previously agrees.

5.4 Use of the Center Address: The Client may use the Center address as its business address. Any other uses are prohibited without the Provider's prior written consent.

6. Compliance

6.1 Comply with the law: The Client and the Provider must comply with all relevant laws and regulations in the conduct of its business in relation to this agreement. The Client must do nothing illegal in connection with its use of the Business Center. The Client must not do anything that may interfere with the use of the Center by the Provider or by others, (including but not limited to political campaigning or immoral activity), cause any nuisance or annoyance, increase the insurance premiums the Provider has to pay, or cause loss or damage to the Provider (including damage to reputation) or to the owner of any interest in the building which contains the Center the Client is using. Both the Client and the Provider shall comply at all times with all relevant anti-bribery and anti-corruption laws.

6.2 If the Provider has been advised by any government authority or other legislative body that it has reasonable suspicion that the Client is conducting criminal activities from the Center then the Provider shall be entitled to terminate this agreement with immediate effect.

6.3 The Client acknowledges that (a) the terms of this clause are a material inducement in the Provider's execution of this agreement and (b) any violation by the Client of this clause shall constitute a material default by the Client hereunder, entitling the Provider to terminate this agreement, without further notice or procedure.

6.4 The Client acknowledges and accepts that its personal data may be transferred or made accessible to all entities of the Provider, wherever located, for the purposes of providing the services herein.

7. The Provider's Liability

or damage the Client suffers in connection with this agreement, with the services or with the Client's accommodation(s) unless the Provider has acted deliberately or negligently in causing that loss or damage. the Provider is not liable for any loss as a result of the Provider's failure to provide a service as a result of mechanical breakdown, strike, termination of the Provider's interest in the building containing the Center or otherwise unless the Provider does so deliberately or is negligent. In no event shall the Provider be liable for any loss or damage until the Client provides the Provider written notice and gives the Provider a reasonable time to put it right. If the Provider is liable for failing to provide the Client with any service under this agreement then subject to the exclusions and limits set out immediately below the Provider will pay any actual and reasonable expenses the Client has incurred in obtaining that service from an alternative source. If the Client believes the Provider has failed to deliver a service consistent with these terms and conditions the Client shall provide the Provider written notice of such failure and give the Provider a reasonable period to put it right.

7.2. EXCLUSION OF CONSEQUENTIAL LOSSES, ETC.: THE PROVIDER WILL NOT IN ANY CIRCUMSTANCES HAVE ANY LIABILITY FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA, THIRD PARTY CLAIMS OR ANY CONSEQUENTIAL LOSS UNLESS THE PROVIDER OTHERWISE AGREES IN WRITING. THE PROVIDER STRONGLY ADVISES THE CLIENT TO INSURE AGAINST ALL SUCH POTENTIAL LOSS, DAMAGE, EXPENSE OR LIABILITY.

7.3. Financial limits to the Provider's liability: In all cases, the Provider's liability to the Client is subject to the following limits:

- Without limit for personal injury or death;
- Up to a maximum of £1 million / USD$2 million / €1.3 million (or local equivalent) for any one event or series of connected events for damage to the Client's personal property except in Turkey where it will be up to a maximum of the monthly office fee over the current term;
- Up to a maximum equal to 125% of the total fees paid between the date the Client moved into its accommodation(s) and the date on which the claim in question arises or £50,000 / USD$100,000 / €66,000 (or local equivalent) whichever is the higher, in respect of any other loss or damage except in Turkey where it will be up to a maximum of the monthly office fee over the current term.

8. Fees

8.1 Taxes and duty charges: The Client agrees to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which it is required to pay to any governmental authority (and, at the Provider's request, will provide to the Provider evidence of such payment) and (ii) any taxes paid by the Provider to any governmental authority that are attributable to the accommodation(s), including, without limitation, any gross receipts, rent and occupancy taxes, tangible personal property taxes, stamp tax or other documentary taxes and fees.

8.2 Service Retainer/Deposit: The Client will be required to pay a service retainer/deposit equivalent to two months' of the monthly office fee (plus VAT/Tax where applicable) upon entering into this agreement unless a different amount is specified on the front of this agreement. This will be held by the Provider without generating interest as security for performance of all the Client's obligations under this agreement. The service retainer/deposit or any balance will be returned to the Client when the Client has settled its account which includes deducting outstanding fees and other costs due to the Provider.

8.3 The Provider may require the Client to pay an increased retainer if outstanding fees exceed the service retainer/deposit held and/or the Client frequently fails to pay the Provider when due.

8.4 Payment: The Provider is continually striving to reduce its environmental impact and supports its clients in doing the same. Therefore the Provider will send all invoices electronically (where allowed by law) and the Client will make payments via an automated method such as Direct Debit or Credit Card, wherever local banking systems permit unless another form of payment is offered to the Client as a qualified and current Key Account. All amounts payable by the Client under this agreement may be assigned to other members of the Provider's group.

8.5 Late payment: If the Client does not pay fees when due, a fee

Supplemental #2
June 15, 2018
11:27 A.M.

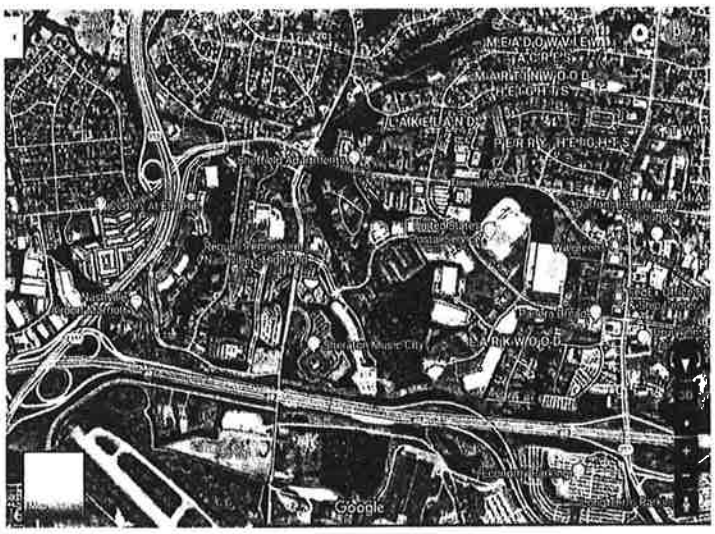
Supplemental Response:

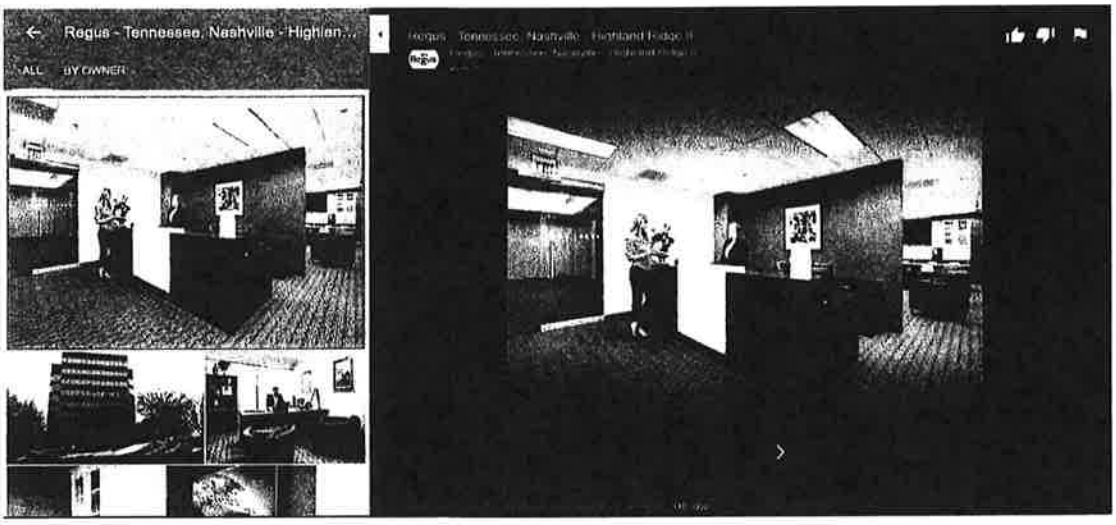
5. Section A, Project Details, Item 6.B.1 (Plot Plan) and 6.B.2

Supplemental Attachment 8

Office Space Description

Supplemental #2
June 15, 2018
11:27 A.M.





Section B

Supplemental

Supplemental Response:

7. Section B. Need, Item 1 (Specific Criteria: Home Health Services)

Supplemental Attachment 9

3-Year Need Projection

Joint Annual Report of Home Health Agencies - 2017 Final
Comparison of Population Based Need Projection vs. Actual Utilization (2020 vs. 2017)**

Service Area	Agencies Report Serving	Total Patients Served	Estimated 2017 Pop.	Use Rate	Projected 2020 Pop.	Projected Capacity	Projected Need (018 x 2020 Pop.)	Need or (Surplus) for 2020
Tennessee	1,530	171,797	6,886,441	0.0249471389	7,112,424	177,435	106,686	(70,748)
Anderson	20	2,375	78,026	0.0304385718	79,061	2,407	1,186	(1,221)
Bedford	20	1,563	50,301	0.0310729409	51,961	1,615	779	(835)
Benton	12	773	16,700	0.0462874251	16,741	775	251	(524)
Bledsoe	12	301	13,333	0.0225755644	13,481	304	202	(102)
Blount	20	2,786	134,882	0.0206550911	139,725	2,886	2,096	(790)
Bradley	19	2,815	106,600	0.0264071295	109,706	2,897	1,646	(1,251)
Campbell	21	1,106	41,559	0.0266127674	41,787	1,112	627	(485)
Cannon	14	873	14,562	0.0599505562	14,838	890	223	(667)
Carroll	15	1,543	28,744	0.0536807682	28,782	1,545	432	(1,113)
Carter	12	1,811	59,848	0.0302599920	60,733	1,838	911	(927)
Cheatham	25	850	41,038	0.0207125104	41,692	864	625	(238)
Chester	13	505	18,450	0.0273712737	18,978	519	285	(235)
Claiborne	16	1,174	34,038	0.0344908632	34,713	1,197	521	(677)
Clay	8	236	7,884	0.0299340436	7,875	236	118	(118)
Cocke	14	1,237	37,163	0.0332857950	37,663	1,254	565	(689)
Coffee	18	2,773	56,423	0.0491466246	57,865	2,844	868	(1,976)
Crockett	11	623	14,936	0.0417113016	15,080	629	226	(403)
Cumberland	15	1,672	62,847	0.0266042930	65,575	1,745	984	(761)
Davidson	32	12,462	689,338	0.0180782142	714,756	12,922	10,721	(2,200)
Decatur	14	629	11,992	0.0524516344	12,077	633	181	(452)
DeKalb	15	962	19,796	0.0485956759	20,206	982	303	(679)
Dickson	20	1,318	54,315	0.0242658566	56,210	1,364	843	(521)
Dyer	11	2,225	39,458	0.0563890719	39,872	2,248	598	(1,650)
Fayette	18	793	45,626	0.0173804410	48,510	843	728	(115)
Fentress	9	722	18,957	0.0380861951	19,309	735	290	(446)
Franklin	17	1,311	42,255	0.0310259141	42,681	1,324	640	(684)
Gibson	18	2,044	51,668	0.0395602694	52,438	2,074	787	(1,288)
Giles	11	908	30,385	0.0298831660	30,691	917	460	(457)
Grainger	19	975	24,073	0.0405018070	24,577	995	369	(627)
Greene	19	2,135	73,075	0.0292165583	74,656	2,181	1,120	(1,061)
Grundy	14	475	13,999	0.0339309951	14,088	478	211	(267)
Hamblen	18	2,640	65,774	0.0401374403	67,028	2,690	1,005	(1,685)
Hamilton	18	8,700	359,331	0.0242116600	368,666	8,926	5,530	(3,396)
Hancock	10	434	6,970	0.0622668580	7,007	436	105	(331)
Hardeman	14	836	27,287	0.0306372998	27,278	836	409	(427)
Hardin	15	1,141	26,618	0.0428657300	26,783	1,148	402	(746)
Hawkins	18	1,905	59,043	0.0322646207	59,784	1,929	897	(1,032)
Haywood	12	538	18,348	0.0293219969	18,128	532	272	(260)
Henderson	14	1,272	29,595	0.0429802331	30,298	1,302	454	(848)
Henry	11	1,355	33,605	0.0403213807	34,055	1,373	511	(862)
Hickman	18	664	26,619	0.0249445885	27,363	683	410	(272)
Houston	12	234	8,943	0.0261657162	9,157	240	137	(102)
Humphreys	14	631	19,042	0.0331372755	19,185	636	288	(348)
Jackson	10	344	12,191	0.0282175375	12,375	349	186	(164)
Jefferson	21	1,609	56,406	0.0285253342	58,372	1,665	876	(790)
Johnson	8	657	18,876	0.0348061030	19,112	665	287	(379)
Knox	25	9,452	472,075	0.0200222422	488,993	9,791	7,335	(2,456)
Lake	7	434	8,377	0.0518085233	8,579	444	129	(316)
Lauderdale	12	1,045	28,799	0.0362859822	29,186	1,059	438	(621)
Lawrence	12	1,479	43,344	0.0341223699	43,849	1,496	658	(838)
Lewis	9	350	12,834	0.0272713106	13,072	356	196	(160)

Source: Tennessee Department of Health, Division of Policy, Planning and Assessment

January 2018

Supplemental #2

June 15, 2018

Joint Annual Report of Home Health Agencies - 2017 Final

Comparison of Population Based Need Projection vs. Actual Utilization (2020 vs. 2017)**

Service Area	Agencies Report Serving	Total Patients Served	Estimated 2017 Pop.	Use Rate	Projected 2020 Pop.	Projected Capacity	Projected Need (.016 x 2020 Pop.)	Need or (Surplus) for 2020
Lincoln	14	1,110	34,891	0.0318133616	35,469	1,128	532	(596)
Loudon	24	1,536	55,192	0.0278301203	57,923	1,612	869	(743)
McMinn	17	871	54,783	0.0158990928	55,724	886	836	(50)
McNairy	23	2,598	27,337	0.0950360318	27,760	2,638	416	(2,222)
Macon	18	1,343	23,639	0.0568128939	24,202	1,375	363	(1,012)
Madison	13	1,295	104,031	0.0124482126	106,352	1,324	1,595	271
Marion	16	597	29,649	0.0201355864	30,129	607	452	(155)
Marshall	18	3,094	33,491	0.0923830283	34,648	3,201	520	(2,681)
Maury	17	717	89,512	0.0080100992	92,944	744	1,394	650
Meigs	17	386	12,285	0.0314204314	12,462	392	187	(205)
Monroe	16	1,414	48,511	0.0291480283	50,062	1,459	751	(708)
Montgomery	23	3,163	206,595	0.0153101479	221,620	3,393	3,324	(69)
Moore	9	65	6,869	0.0094628039	7,056	67	106	39
Morgan	18	445	23,626	0.0188351816	24,288	457	364	(93)
Obion	12	1,445	31,655	0.0456483968	31,559	1,441	473	(967)
Overton	10	667	23,678	0.0281696089	24,291	684	364	(320)
Perry	6	332	8,315	0.0399278413	8,466	338	127	(211)
Pickett	7	218	5,223	0.0417384645	5,264	220	79	(141)
Polk	13	476	17,538	0.0271410651	17,812	483	267	(216)
Putnam	15	3,035	80,838	0.0375442243	84,087	3,157	1,261	(1,896)
Rhea	17	683	34,262	0.0199346214	35,216	702	528	(174)
Roane	21	1,758	55,813	0.0314980381	56,301	1,773	845	(929)
Robertson	28	1,597	75,017	0.0212885079	78,659	1,675	1,180	(495)
Rutherford	32	5,155	323,441	0.0159379918	350,488	5,586	5,257	(329)
Scott	14	709	22,976	0.0308582869	23,224	717	348	(368)
Sequatchie	17	367	16,125	0.0227596899	16,943	386	254	(131)
Sevier	18	1,862	102,998	0.0180780209	108,468	1,961	1,627	(334)
Shelby	27	17,580	964,804	0.0182213175	981,022	17,876	14,715	(3,160)
Smith	15	814	20,378	0.0399450388	20,833	832	312	(520)
Stewart	12	351	14,118	0.0248618785	14,402	358	216	(142)
Sullivan	15	5,572	159,191	0.0350019788	159,749	5,592	2,396	(3,195)
Sumner	30	4,207	181,647	0.0231603054	190,261	4,407	2,854	(1,553)
Tipton	17	1,122	68,247	0.0164402831	71,196	1,170	1,068	(103)
Trousdale	16	261	8,477	0.0307891943	8,739	269	131	(138)
Unicoi	10	638	18,921	0.0337191480	19,150	646	287	(358)
Union	14	390	20,020	0.0194805195	20,320	396	305	(91)
Van Buren	9	203	5,661	0.0358593888	5,686	204	85	(119)
Warren	16	2,063	41,019	0.0502937663	41,446	2,084	622	(1,463)
Washington	15	3,723	135,611	0.0274535252	140,905	3,868	2,114	(1,755)
Wayne	10	753	17,491	0.0430507118	17,642	760	265	(495)
Weakley	14	1,175	36,205	0.0324540809	36,360	1,180	545	(635)
White	17	1,519	27,781	0.0546776574	28,541	1,561	428	(1,132)
Williamson	33	3,572	220,746	0.0161814937	241,597	3,909	3,624	(285)
Wilson	27	3,221	131,486	0.0244969046	138,561	3,394	2,078	(1,316)

*Most recent year of Joint Annual Report data for Home Health Agencies

**Data is projected three years from the latest available year of final Home Health Joint Annual Report data.

Population Data Source: The University of Tennessee Center for Business and Economic Research Projection Data Files, reassembled by the Tennessee Department of Health, Division of Policy, Planning and Assessment.

Note: Population data may not match University of Tennessee data exactly due to rounding.

Source: Tennessee Department of Health, Division of Policy, Planning and Assessment

January 2018

Supplemental Response:

8. Section B. Need, Item 1 (Specific Criteria: Home Health Services) (1) Determination of Need

Supplemental Attachment 10

Certified Counties for Existing Similar Home Health Agencies

Certified Counties for Existing Similar HHAs

Home Health Agency	Certified Counties
Cumberland River Homecare (14024)	Clay, Cumberland, DeKalb, Fentress, Jackson, Macon, Overton, Pickett, Putnam, White
Suncrest Home Health (19324)	Cheatham, Davidson, Dickson, Macon, Montgomery, Robertson, Rutherford, Smith, Sumner, Trousdale, Williamson, Wilson
Suncrest Home Health (13032)	Campbell, Claiborne, Cocke, Grainger, Greene, Hamblen, Hancock, Hawkins, Jefferson, Sullivan, Union
Suncrest Homes Health (21024)	Cannon, DeKalb, Putnam, Smith, Warren, White, Wilson
Home Care Solutions (19544)	All Counties
Coram CVS Specialty Infusion Services (19734)	Bedford, Bledsoe, Cannon, Cheatham, Clay, Coffee, Cumberland, Davidson, DeKalb, Dickson, Franklin, Giles, Grundy, Hamilton, Hickman, Humphreys, Jackson, Lawrence, Lewis, Lincoln, Macon, Marion, Marshall, Maury, Montgomery, Overton, Putnam, Rhea, Robertson, Rutherford, Sequatchie, Smith, Sumner, Trousdale, Warren, White, Williamson, Wilson
Coram CVS Specialty Infusion Services (79556)	Gibson, Obion, Shelby, Tipton,
Vanderbilt Affiliated Walgreens Services (19994)	Bedford, Cannon, Cheatham, Coffee, Davidson, DeKalb, Dickson, Dyer, Franklin, Giles, Grainger, Jefferson, Knox, Lawrence, Lincoln, Madison, Marshall, Maury, Montgomery, Putam, Roane, Robertson, Rutherford, Shelby, Sullivan, Sumner, Trousdale, White, Williamson, Wilson,
Procare Home Health Services (30051)	Carter, Greene, Johnson, Sullivan, Unicoi, Washington
Maxim Healthcare Services (33433)	Bradley, Grundy, Hamilton, McMinn, Marion, Meigs, Rhea, Sequatchie
Henry County Medical Center Home Health (40075)	Benton, Carroll, Cheatham, Dickson, Henry, Hickman, Houston, Humphreys, Montgomery, Robertson, Stewart, Weakley
NHC Homecare (60024)	Bedford, Cheatham, Davidson, Dickson, Giles, Hardin, Hickman, Houston, Humphreys, Lawrence, Lewis, Lincoln, Marshall, Maury, Montgomery, Moore, Perry, Rutherford, Stewart, Wayne, Williamson

Supplemental #2
June 15, 2018
11:27 A.M.

Still Waters Home Health Agency (79526)	Shelby
Pentec Health, Inc. (19744)	Anderson, Bledsoe, Blount, Bradley, Campbell, Claiborne, Cocke, Cumberland, Fentress, Franklin, Gundy, Hamblen, Hamilton, Jefferson, Knox, Loudon, McMinn, Marion, Monroe, Montgomery, Morgan, Polk, Putnam, Rhea, Rutherford, Sequatchie, Sevier, Union, Washington, White,

Supplemental Response:

9. Section B, Need, Item 1.a. (Project Specific Criteria-Home Health Services) Item #4 County Need Standard

Supplemental Attachment 11

Tennessee Providers Requesting Additional Home Care Service Agencies

CPS

COMPREHENSIVE PAIN SPECIALISTS

Tennessee Department of Health
710 James Robertson Pkwy
Nashville, TN 37243

May 30, 2018

Re: Additional Home Care Service Certificate of Need

Dear Sir or Madam,

As an advanced practice nurse in the state of Tennessee, I am writing in support of AIS HealthCare's request to provide home care services for patients with implanted pain pumps living in the great state of Tennessee. As you are most keenly aware, we are in the midst of combatting an opioid epidemic crisis, across this country and in Tennessee. One of the tools pain managers may use in assisting to manage pain and reduce opioid use is an implanted pain pump. Implanted pain pumps (intrathecal infusion therapy) require highly skilled practitioners and nurses to manage this therapy. In my experience, the home care services which are prevalent in TN have been unable to accept these patients due to the training and skills required by the nursing staff.

Allowing AIS HealthCare service option will improve access to appropriately and professionally skilled care for patients who need intrathecal infusion therapy services and have transportation and/or mobility limitations. Providing quality care services offered in the home increases safety and care for these patients. With more home care services, patients in these vulnerable situations do not have to worry about the potential logistical challenges associated with receiving their infusion refill in our office, as missing their scheduled refills may result in short- or long-term medical problems, emergency room visits, medical condition exacerbations, increased risk to the patient's overall safety and well-being, and ultimately device failure may occur requiring surgical intervention.

The intent of this home care service is to provide an improved quality of life and function for patients, home safety monitoring, and highly skilled nurses to complete these specialized procedures.

While highly efficacious, there are substantial complexities associated with intrathecal infusions. Patient pumps must be refilled in a timely manner by qualified clinicians as mentioned above to avoid unnecessary emergent transport by ambulance or costly and critical interventions. Further as alluded to above, the majority of home care agencies are not trained and qualified to perform these specialty intrathecal pump services and could lead to increased cost and adverse outcomes to this fragile population, which I have unfortunately witnessed in my patient population when poorly trained nursing care failed to accurately refill one of these devices. These pumps are highly specialized therapies which require extensive training and competencies to increase the patient safety and outcomes. AIS HealthCare thoroughly trains each and every one of their nurses with competency checks and multiple safety check points and algorithms. I heartily endorse their endeavors to provide this highly specialized and necessary therapy, and respectfully request your consideration of adding them to Tennessee's home care provider options.

Sincerely,

S Trent, APRN

Sarah Trent, MSN, APRN-BC, APN #10907

Supplemental #2
June 15, 2018
11:27 A.M.

CPS
COMPREHENSIVE PAIN SPECIALISTS
776 WEATHERLY DRIVE, SUITE 8, CLARKSVILLE, TN 37043 | P 931.919.4330 | F 931.919.4331 | WWW.CPSPAIN.COM

Dear Tennessee Department of Health,

I am writing to support an increased number of home care services for patients with implanted pain pumps or immunoglobin infusion needs. An important and necessary element for care of these chronic patients is the provision of highly trained home nursing services for patients in the state of Tennessee.

More home care service options will improve access to care for patients who need intrathecal or immunological infusion therapy services. Providing quality care services offered in the home increases access to care for these patients. Additionally, home care greatly benefits patients who do not live in close proximity of their doctor's office, who do not have their own source of transportation or who do not have access to public transportation. With more home care services, patients do not have to worry about the potential logistical challenges associated with receiving their infusion refill in our office. More importantly, it will likely decrease the safety risks caused for patients who are unable to make their refill appointments.

The intent is to provide an improved Quality of Life and function for patients, home safety monitoring, and highly skilled nurses to complete these specialized procedures.

While highly efficacious, there are substantial complexities associated with intrathecal infusions. Patient pumps must be refilled in a timely manner by qualified clinicians. to avoid, unnecessary emergent transport by ambulance or costly and critical interventions. The majority of home care agencies are not trained and qualified to perform these specialty intrathecal pump services and could lead to increased cost and adverse outcomes to this fragile population. These are highly specialized therapies which require extensive training and competencies to increase the patient safety and outcomes.

Access to more home care services for intrathecal and immunoglobulin infusion patients could increase their quality of life. Please consider adding more home care providers that offer this highly specialized and necessary therapy.

Sincerely,

Rebekah Pierce APRN

Rebekah Pierce APRN

CL5824201 4

Supplemental #2
June 15, 2018
11:27 A.M.

ADVANCED SPINE
OF HEALTHSTAR PHYSICIANS

DENNIS G. HARRIS, MD

May 30, 2018

Dear Tennessee Department of Health,

I am writing to support an increased number of home care services for patients with implanted pain pumps or immunoglobin infusion needs. An important and necessary element for care of these chronic patients is the provision of highly trained home nursing services for patients in the state of Tennessee.

More home care service options will improve access to care for patients who need intrathecal or immunological infusion therapy services. Providing quality care services offered in the home increases access to care for these patients. Additionally, home care greatly benefits patients who do not live in close proximity of their doctor's office, who do not have their own source of transportation or who do not have access to public transportation. With more home care services, patients do not have to worry about the potential logistical challenges associated with receiving their infusion refill in our office. More importantly, it will likely decrease the safety risks caused for patients who are unable to make their refill appointments.

The intent is to provide an improved Quality of Life and function for patients, home safety monitoring, and highly skilled nurses to complete these specialized procedures.

While highly efficacious, there are substantial complexities associated with intrathecal infusions. Patient pumps must be refilled in a timely manner by qualified clinicians. to avoid, unnecessary emergent transport by ambulance or costly and critical interventions. The majority of home care agencies are not trained and qualified to perform these specialty intrathecal pump services and could lead to increased cost and adverse outcomes to this fragile population. These are highly specialized therapies which require extensive training and competencies to increase the patient safety and outcomes.

Access to more home care services for intrathecal and immunoglobulin infusion patients could increase their quality of life. Please consider adding more home care providers that offer this highly specialized and necessary therapy.

Sincerely,

420 W. MORRIS BLVD., SUITE 130 • MORRISTOWN, TN 37813
☎ 423.581.3939 🖷 423.839.0550

Supplemental #2
June 15, 2018
11:27 A.M.

PAIN MEDICINE ASSOCIATES, P.C.

William T. Williams, M.D.
Sameh A. Ward, M.D.
David Dahl, M.D.
Michael Wilkinson, M.D.
C. Marcus Cooper, Ph.D.
Kristina Bagley, F.N.P.
Holly Broadwater, F.N.P.
Cheryl Conrad, F.N.P.
Shannon Hollowell, F.N.P.
Benjamin A. Meeks, F.N.P.
John Powell, P.A.-C
Vickie Stufflestreet, L.P.N.-C
Tony Villanueva, P.T.

May 30, 2018

Tennessee Department of Health
710 James Robertson Pkwy
Nashville, TN 37243

Dear Tennessee Department of Health:

I am writing to support an increased number of home care services for patients with implanted pain pumps or immunoglobin infusion needs. An important and necessary element for care of these chronic patients is the provision of highly-trained home nursing services for patients in the state of Tennessee.

More home care service options will improve access to care for patients who need intrathecal or immunological infusion therapy services. Providing quality care services offered in the home increases access to care for these patients. Additionally, home care greatly benefits patients who do not live in close proximity to their doctor's office, who do not have their own source of transportation, or who do not have access to public transportation. With more home care services, patients do not have to worry about the potential logistical challenges associated with receiving their infusion refill in our office. More importantly, it will likely decrease the safety risks caused for patients who are unable to make their refill appointments. The intent is to provide an improved quality of life and function for patients, home safety monitoring, and highly-skilled nurses to complete these specialized procedures.

While highly efficacious, there are substantial complexities associated with intrathecal infusions. Patient pumps must be refilled in a timely manner by qualified clinicians to avoid unnecessary emergent transport by ambulance or costly and critical interventions. The majority of home care agencies are not trained and qualified to perform these specialty intrathecal pump services and could lead to increased cost and adverse outcomes to this fragile population. These are highly specialized therapies which require extensive training and competencies to increase the patient safety and outcomes.

Continued

101 MedTech Parkway, Suite 200
Johnson City, Tennessee 37604
Phone: (423) 232-6120
Fax: (423) 232-6125

2202 North John B. Dennis Hwy,
Suite 200
Kingsport, Tennessee 37660
Phone: (423) 392-6690
Fax: (423) 392-6695

240 Medical Park Blvd.,
Suite 1500
Bristol, Tennessee 37620
Phone: (423) 968-9313
Fax: (423) 968-9696

Supplemental #2
June 15, 2018
11:27 A.M.

Access to more home care services for intrathecal and immunoglobulin infusion patients could increase their quality of life. Please consider adding more home care providers that offer this highly specialized and necessary therapy.

Sincerely,

Sameh A. Ward, M.D.
Pain Medicine Associates, P.C.

Supplemental #2
June 15, 2018
11:27 A.M.

PAIN MEDICINE ASSOCIATES, P.C.

William T. Williams, M.D.
Sameh A. Ward, M.D.
David Dahl, M.D.
Michael Wilkinson, M.D.
C. Marcus Cooper, Ph.D.
Kristina Bagley, F.N.P.
Holly Broadwater, F.N.P.
Cheryl Conrad, F.N.P.
Shannon Hollowell, F.N.P.
Benjamin A. Meeks, F.N.P.
John Powell, P.A.-C
Vickie Stufflestreet, L.P.N.-C
Tony Villanueva, P.T.

May 30, 2018

Tennessee Department of Health
710 James Robertson Pkwy
Nashville, TN 37243

Dear Tennessee Department of Health:

I am writing to support an increased number of home care services for patients with implanted pain pumps or immunoglobin infusion needs. An important and necessary element for care of these chronic patients is the provision of highly-trained home nursing services for patients in the state of Tennessee.

More home care service options will improve access to care for patients who need intrathecal or immunological infusion therapy services. Providing quality care services offered in the home increases access to care for these patients. Additionally, home care greatly benefits patients who do not live in close proximity to their doctor's office, who do not have their own source of transportation, or who do not have access to public transportation. With more home care services, patients do not have to worry about the potential logistical challenges associated with receiving their infusion refill in our office. More importantly, it will likely decrease the safety risks caused for patients who are unable to make their refill appointments. The intent is to provide an improved quality of life and function for patients, home safety monitoring, and highly-skilled nurses to complete these specialized procedures.

While highly efficacious, there are substantial complexities associated with intrathecal infusions. Patient pumps must be refilled in a timely manner by qualified clinicians to avoid unnecessary emergent transport by ambulance or costly and critical interventions. The majority of home care agencies are not trained and qualified to perform these specialty intrathecal pump services and could lead to increased cost and adverse outcomes to this fragile population. These are highly specialized therapies which require extensive training and competencies to increase the patient safety and outcomes.

Continued

101 MedTech Parkway, Suite 200
Johnson City, Tennessee 37604
Phone: (423) 232-6120
Fax: (423) 232-6125

2202 North John B. Dennis Hwy,
Suite 200
Kingsport, Tennessee 37660
Phone: (423) 392-6690
Fax: (423) 392-6695

240 Medical Park Blvd.,
Suite 1500
Bristol, Tennessee 37620
Phone: (423) 968-9313
Fax: (423) 968-9686

Supplemental #2
June 15, 2018
11:27 A.M.

Access to more home care services for intrathecal and immunoglobulin infusion patients could increase their quality of life. Please consider adding more home care providers that offer this highly specialized and necessary therapy.

Sincerely,

W. Turney Williams, M.D.
Pain Medicine Associates, P.C.

Supplemental Response:

10. Section B. Need, Item 1 (Specific Criteria: Home Health Services) (5) Current Service Area Utilization

Supplemental Attachment 12

Revised Table for Attachment A.1

Current Services Area Utilization

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Anderson	78,387	79,061	0.9	62,000	62,772	1.2	20.60	43.3	44,241	12,747	17.2%	7,849	10.01%
Bedford	50,860	51,961	2.2	37,735	38,657	2.4	25.60	36.9	43,819	7,423	16.3%	5,055	9.94%
Benton	16,711	16,741	0.2	13,666	13,764	0.7	17.78	46.6	33,611	3,614	22.6%	2,109	12.62%
Bledsoe	13,394	13,481	0.6	10,825	10,935	1.0	18.88	43.0	38,535	3,050	23.7%	1,524	11.38%
Blount	136,505	139,725	2.4	108,596	111,741	2.9	20.04	43.0	49,532	16,793	13.6%	10,487	7.68%
Bradley	107,651	109,706	1.9	83,908	85,865	2.3	21.73	39.3	43,721	18,291	18.4%	10,368	9.63%
Campbell	41,654	41,787	0.3	33,167	33,459	0.9	19.93	43.5	33,628	8,821	22.4%	6,911	16.59%
Cannon	14,658	14,838	1.2	11,739	11,956	1.8	19.42	42.1	43,654	2,208	16.2%	1,569	10.70%
Carroll	28,753	28,782	0.1	22,648	22,726	0.3	21.05	42.9	36,212	5,441	19.8%	6,052	21.05%
Carter	60,154	60,733	1.0	48,587	49,243	1.4	18.92	44.	33,177	13,110	23.9%	6,799	11.30%
Cheatham	41,269	41,692	1.0	32,140	32,717	1.8	21.52	40.2	53,179	5,061	12.9%	3,300	8.00%
Chester	18,633	18,978	1.9	14,720	15,098	2.6	20.48	37.1	42,376	2,911	17.9%	1,855	9.96%
Claiborne	34,263	34,713	1.3	27,727	28,307	2.1	18.45	42.3	33,428	6,771	22.3%	4,997	14.58%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Clay	7,876	7,785	0.0	6,337	6,350	0.2	18.43	47.4	28,147	1,904	24.8%	41	0.52%
Cocke	37,335	37,663	0.9	29,961	30,348	1.3	19.42	44.5	31,081	9,081	26.1%	5,918	15.85%
Coffee	56,909	57,865	1.7	43,634	44,534	2.1	23.03	40.1	45,456	8,437	15.9%	6,295	11.06%
Crockett	14,982	15,080	0.7	11,412	11,526	1.0	23.36	39.6	38,043	2,602	18.3%	1,757	11.73%
Cumberland	63,778	65,575	2.8	53,032	54,808	3.3	16.42	50.1	40,123	9,075	16.0%	6,091	9.55%
Davidson	698,061	714,756	2.4	528,965	539,109	1.9	24.57	34.2	50,484	114,238	17.7%	58,291	8.35%
Decatur	12,029	12,077	0.4	9,619	9,705	0.9	19.64	45.5	38,180	2,399	20.9%	1,489	12.38%
Dekalb	19,936	20,206	1.4	15,626	15,897	1.7	21.33	40.9	37,640	4,152	22.2%	2,495	12.52%
Dickson	54,959	56,210	2.3	42,109	43,271	2.8	23.01	40.0	47,137	8,019	15.9%	5,099	9.28%
Dyer	39,607	39,872	0.7	30,291	30,563	0.9	23.34	40.3	42,833	6,915	18.6%	5,063	12.78%
Fayette	46,608	48,510	4.1	36,749	38,496	4.8	20.64	44.4	55,972	5,774	15.0%	3,308	7.10%
Fentress	19,082	19,309	1.2	15,154	15,440	1.9	20.03	44.3	31,714	4,107	23.3%	3,221	16.88%
Franklin	42,395	42,681	0.7	33,998	34,523	1.5	19.11	41.9	44,837	6,397	16.2%	3,896	9.19%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Gibson	51,934	52,438	1.0	39,562	40,041	1.2	23.68	40.3	38,854	9,039	18.7%	6,233	12.00%
Giles	30,492	30,691	0.7	24,175	24,434	1.1	20.38	42.9	40,635	4,721	16.7%	3,165	10.38%
Grainger	24,244	24,577	1.4	19,320	19,677	1.8	19.94	44.2	37,522	4,578	20.2%	3,083	12.72%
Greene	73,620	74,656	1.4	59,408	60,547	1.9	18.90	44.0	36,711	12,373	18.6%	8,086	10.98%
Grundy	14,040	14,088	0.3	11,189	11,309	1.1	19.72	43.0	28,467	3,718	28.0%	2,428	17.29%
Hamblen	66,195	67,028	1.3	50,192	51,586	1.3	23.03	40.5	39,270	13,112	21.2%	6,975	10.54%
Hamilton	362,471	368,666	1.7	283,457	288,264	1.7	21.81	39.3	49,434	50,631	14.8%	30,468	8.41%
Hancock	6,981	7,007	0.4	5,594	5,641	0.8	19.45	44.3	27,973	1,757	27.3%	1,239	17.75%
Hardeman	27,284	27,278	0.0	22,014	22,135	0.5	18.85	39.9	33,566	5,285	23.7%	3,543	11.99%
Hardin	26,680	26,783	0.4	21,390	21,579	0.9	19.43	45.1	37,244	5,634	22.2%	3,816	14.30%
Hawkins	59,311	59,784	0.8	47,294	48,045	1.6	19.64	43.8	37,883	10,706	19.2%	6,880	11.60%
Haywood	18,274	18,128	-0.8	13,990	13,950	-0.3	23.04	40.4	35,094	3,744	21.0%	2,676	14.64%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Henderson	29,836	30,298	1.5	22,947	23,400	2.0	22.76	40.4	41,478	5,703	20.7%	3,551	11.90%
Henry	33,771	34,055	0.8	26,925	27,278	1.3	19.90	45.1	38,378	6,151	19.4%	3,842	11.38%
Hickman	26,876	27,363	1.8	21,460	21,965	2.4	19.72	40.4	37,546	5,181	22.9%	2,952	10.98%
Houston	9,014	9,157	1.6	7,055	7,210	2.2	21.26	43.5	40,680	1,675	20.9%	1,054	11.69%
Humphreys	19,090	19,185	0.5	15,033	15,217	1.2	20.68	41.7	40,995	3,308	18.5%	2,191	11.48%
Jackson	12,251	12,375	1.0	10,104	10,278	1.7	16.94	46.1	32,676	2,835	25.0%	1,501	12.25%
Jefferson	57,072	58,372	2.3	45,484	46,760	2.8	19.89	42.7	43,673	7,724	15.2%	6,026	10.56%
Johnson	18,952	19,112	0.8	15,734	15,968	1.5	16.45	44.8	30,180	4,313	26.9%	2,362	12.46%
Knox	477,780	488,993	2.3	372,202	381,171	2.4	22.05	37.3	50,366	70,612	16.2%	36,512	7.64%
Lake	8,441	8,579	1.6	7,234	7,392	2.2	13.84	40.7	29,893	1,413	29.2%	1,192	14.12%
Lauderdale	28,930	29,186	0.9	22,299	22,606	1.4	22.54	37.6	32,353	6,014	24.7%	3,789	13.10%
Lawrence	43,518	43,849	0.8	33,251	33,665	1.2	23.22	39.9	40,457	8,136	19.5%	5,216	11.99%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Lewis	12,912	13,072	1.2	10,160	10,371	2.1	20.66	43.6	36,920	2,384	20.4%	1,453	11.25%
Lincoln	35,104	35,469	1.0	27,369	27,797	1.6	21.63	42.9	41,038	6,123	18.5%	3,601	10.26%
Loudon	56,118	57,923	3.2	45,920	47,612	3.7	17.80	47.2	52,995	6,767	13.5%	4,109	7.32%
McMinn	55,100	55,724	1.1	43,501	44,132	1.5	20.80	42.9	38,661	10,012	19.5%	3,032	5.50%
McNairy	27,486	27,760	1.0	21,565	21,900	1.6	21.11	42.9	31,956	5,916	23.1%	11,249	40.93%
Macon	23,838	24,202	1.5	18,318	18,701	2.1	22.72	39.6	34,098	4,167	18.6%	3,032	12.72%
Madison	104,799	106,352	1.5	79,760	81,151	1.7	23.70	37.8	44,237	18,345	19.4%	11,249	10.73%
Marion	29,810	30,129	1.1	23,795	24,190	1.7	19.71	43.2	41,477	5,374	19.2%	3,466	11.63%
Marshall	33,885	34,648	2.3	26,086	26,833	2.9	22.56	39.6	44,900	4,655	15.1%	3,097	9.14%
Maury	90,666	92,944	2.5	69,267	71,249	2.9	23.34	39.1	49,597	12,413	14.7%	8,169	9.01%
Meigs	12,345	12,462	0.9	10,073	10,242	1.7	17.81	43.9	35,209	2,160	18.8%	1,577	12.77%
Monroe	49,048	50,062	2.1	38,893	29,979	2.8	40.12	43.1	37,054	8,575	19.2%	5,672	11.56%
Montgomery	211,602	221,620	4.7	149,533	156,218	4.5	29.51	30.3	51,528	28,232	15.2%	16,078	7.60%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Moore	6,923	7,056	1.9	5,604	5,754	2.7	18.45	46.5	49,496	644	10.4%	380	5.49%
Morgan	23,848	24,288	1.8	19,441	19,921	2.5	17.98	41.1	39,728	4,415	23.6%	2,280	9.56%
Obion	31,625	31,559	-0.2	24,919	24,940	0.1	20.97	42.5	38,933	6,399	21.1%	3,931	12.43%
Overton	23,885	24,291	1.7	18,772	19,179	2.2	21.04	42.6	35,065	4,340	20.0%	2,641	11.06%
Perry	8,362	8,466	1.2	6,626	6,742	1.8	20.36	43.3	31,274	2,216	28.6%	1,001	11.97%
Pickett	5,237	5,264	0.5	4,357	4,443	2.0	15.60	49.8	39,014	827	16.5%	593	11.32%
Polk	17,627	17,812	1.0	14,103	14,288	1.3	19.78	44.6	41,520	2,918	17.8%	2,124	12.05%
Putman	81,972	84,087	2.6	64,190	65,846	2.6	21.69	36.1	36,350	17,180	24.0%	8,520	10.39%
Rhea	34,582	35,216	1.8	26,899	27,610	2.6	21.60	40.3	38,355	7,160	22.9%	4,224	12.21%
Roane	55,990	56,301	0.6	45,510	45,977	1.0	18.33	46.3	42,299	8,449	16.2%	5,931	10.59%
Robertson	76,231	78,659	3.2	54,400	59,488	3.6	24.37	38.5	56,331	7,067	10.5%	5,650	7.41%
Rutherford	332,411	350,488	5.7	247,473	261,598	5.4	25.36	32.9	58,032	35,764	12.6%	21,094	6.35%
Scott	23,058	23,224	0.7	17,598	17,805	1.2	23.33	38.8	30,897	6,000	27.7%	3,931	17.05%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Sequatchie	16,399	16,943	3.3	12,946	13,442	3.8	20.66	42.5	46,541	2,328	16.1%	1,893	11.54%
Sevier	104,829	108,468	3.5	83,498	86,676	3.8	20.09	42.4	42,586	14,285	15.3%	9,115	8.70%
Shelby	970,212	981,022	1.1	720,465	728,710	1.1	25.72	35.1	46,854	196,471	21.4%	107,590	11.09%
Smith	20,534	20,833	2.2	16,001	16,348	1.5	21.53	41.2	44,272	3,050	16.2%	2,066	10.06%
Stewart	14,210	14,402	2.2	11,369	11,618	1.4	19.33	43.4	41,835	2,520	19.2%	1,558	10.96%
Sullivan	159,393	159,749	0.2	128,541	129,225	0.5	19.10	44.5	40,983	25,982	16.8%	17,100	10.73%
Sumner	184,532	190,261	3.1	141,250	146,486	3.7	23.01	39.5	58,972	16,543	9.7%	12,731	6.90%
Tipton	69,239	71,196	2.8	52,243	54,039	3.4	24.10	37.3	54,650	8,378	13.8%	6,030	8.71%
Trousdale	8,564	8,739	2.0	6,661	6,829	2.5	21.86	39.0	47,667	1,043	13.3%	986	11.51%
Unicoi	19,003	19,150	0.8	15,430	15,615	1.2	18.46	45.6	35,390	3,687	21.0%	2,185	11.50%
Union	20,124	20,320	1.0	15,654	15,892	1.5	21.79	41.5	38,540	4,420	23.5%	2,541	12.63%
Van Buren	5,668	5,686	0.3	4,654	4,694	0.9	17.45	45.8	42,813	1,058	19.1%	691	12.19%
Warren	41,167	41,446	0.7	31,588	31,909	1.1	23.01	39.9	36,245	8,158	20.7%	5,403	13.12%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Washington	137,400	140,905	2.6	110,132	113,097	2.7	19.74	39.7	44,444	20,810	17.1%	12,214	8.89%
Wayne	17,551	17,642	0.5	14,491	14,667	1.2	16.86	41.9	34,008	2,796	18.9%	1,673	9.53%
Weakley	36,300	36,360	0.2	29,283	29,385	0.3	19.18	37.5	38,040	5,962	19.1%	3,543	9.76%
White	28,037	28,541	1.8	22,286	22,815	2.4	20.06	43.5	35,989	4,662	18.1%	3,579	12.77%
Williamson	225,526	241,597	7.1	168,033	182,015	8.3	24.66	39.0	100,140	10,547	5.2%	5,399	2.39%
Wilson	133,865	138,561	3.5	103,160	107,612	4.3	22.33	40.3	63,426	11,266	9.1%	8,474	6.33%
Service Area Total	6,960,524	7,112,424	2.2	5,367,165	5,496,968	2.4	22.71	38.6	48,547	1,100,169	17.2%		
State of TN Total	6,960,524	7,112,424	2.2	5,367,165	5,496,968	2.4	22.71	38.6	48,547	1,100,169	17.2%		

Acknowledgement: Population data was provided by the Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics.

*2016 factfinder.census.gov
Source: U.S. Census Bureau, 2012-2016 American Community Survey
**2017 Revised UTCBER Population Projections Series
Source: The University of Tennessee Center for Business and Economic Research Population Data Files, Reassembled by the Tennessee Department of Health, Division of Policy, Planning and Assessment.
Note: These data will not match the University of Tennessee Data exactly due to rounding.

Facility ID Info			Patients Served and Gross Revenue By Revenue Source -- Medicare				Patients Served and Gross Revenue By Revenue Source -- Medicare Advantage				Patients Served and Gross Revenue By Revenue Source -- UHC Community Plan (Medicaid/Tenncare				Patients Served and Gross Revenue By Revenue Source -- Amerigroup (Medicaid/Tenncare)				Patients Served and Gross Revenue By Revenue Source -- Blue Care (Medicaid/Tenncare)				Tenncare Select (Medicaid/Tenncare)				Tenncare, MCO (not specified)(Medicaid/Tenncare)			
			Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other	
	State ID	Facility Name	County	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours
	13032	Suncrest Home Health	Claiborne	0	0	0	0	0	0	0	0	0	46	0	0	0	0	0	0	0	194	0	0	0	0	0	0	0	0	0	0
	14024	Cumberland River Homecare	Clay	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	19324	Suncrest Home Health	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	43	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	19544	Home Care Solutions	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	19734	Coram CVS Speciality Infusion Services	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	6	0	0	0	0	0	0
	19994	Vanderbilt Affiliated Walgreens Services	Davidson	0	0	0	0	11	0	0	0	0	90	0	0	0	0	116	0	0	0	0	0	0	0	0	0	0	0	0	0
	21024	Suncrest Home Health	DeKalb	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0
	30051	Procare Home Health Services	Greene	50	0	50	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	33433	Maxim Healthcare Services	Hamilton	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40075	Henry County Medical Center Home Health	Henry	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	60024	NHC Homecare	Maury	200		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0
	79526	Still Waters Home Health Agency	Shelby	0	0	1	1	0	0	0	0	0	0	0	0	136	136	0	0	0	0	0	0	0	0	0	0	0	0	0	
	79558	Coram CVS/Specialty Infusion Service	Shelby	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	19744	Pentec Health, Inc.	Davidson	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Supplemental #2
June 15, 2018
11:27 A.M.

Facility ID Info			Patients Served and Gross Revenue By Revenue Source - Other State Medicaid (Medicaid/TennCare)				Patients Served and Gross Revenue By Revenue Source - CoverKids (Medicaid/Tenncare)				Patients Served and Gross Revenue By Revenue Source – TRICARE				Patients Served and Gross Revenue By Revenue Source – Commercial				Patients Served and Gross Revenue By Revenue Source – Self Pay				Patients Served and Gross Revenue By Revenue Source – Home and Community Based Waiver Programs				Patients Served and Gross Revenue By Revenue Source – TN Commission on Aging and Disability			
			Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other	
State ID	Facility Name	County	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours
13032	Suncrest Home Health	Claiborne	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14024	Cumberland River Homecare	Clay	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19324	Suncrest Home Health	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19544	Home Care Solutions	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19734	Coram CVS Speciality Infusion Services	Davidson	0	0	0	0	0	0	0	0	52	276	3	4	240	1228	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19994	Vanderbilt Affiliated Walgreens Services	Davidson	0	0	0	0	0	0	0	0	0	0	40	0	0	0	430	0	0	0	1	0	0	0	0	0	0	0	0	0
21024	Suncrest Home Health	DeKalb	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
30051	Procare Home Health Services	Greene	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
33433	Maxim Healthcare Services	Hamilton	0		0	0	0	0	0	0		0	0	0	0	0	0	0	18	6	0	0	0	0	0	0	0	0	0	0
40075	Henry County Medical Center Home Health	Henry	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
80024	NHC Homecare	Maury	0	0	0		0	0	0	0	0		0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0
79526	Still Waters Home Health Agency	Shelby	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0
79556	Coram CVS/Specialty Infusion Service	Shelby	0	0	0	0	0		0		40	92	10	14	105	96	108	758	0	0	0	0	0	0	0	0	0	0	0	0
19744	Pentec Health, Inc.	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0		0	0	0	0	0	0	0	0

	Facility ID Info			Patients Served and Gross Revenue By Revenue Source – Charity Care				Patients Served and Gross Revenue By Revenue Source – Federal Department of Labor (EEOICP)				Patients Served and Gross Revenue By Revenue Source – Other				Patients Served and Gross Revenue By Revenue Source – Total All Revenue Sources								
				Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Totals				
	State ID	Facility Name	County	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Patients	Visits	Hours	Gross Revenue	Percentage of total
	13032	Suncrest Home Health	Claiborne	0	0	0	0	0	0	0	0	0	203	0	0	0	443	0	0	1937	35510	59404	5715923	100
	14024	Cumberland River Homecare	Clay	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	390	10288	105445	6590015	100
	19324	Suncrest Home Health	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	43	0	0	5437	72976	76970	9264856	100
	19544	Home Care Solutions	Davidson	0	0	0	0	0	0	0	0	14	9	0	0	14	9	0	0	1475	43618	38570	6516442	100
	19734	Coram CVS Speciality Infusion Services	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	294	1510	3	4	35	297	1514	70915	100
	19994	Vanderbilt Affiliated Walgreens Services	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1505	0	296	1505	0	195844	100
	21024	Suncrest Home Health	DeKalb	0	0	0	0	0	0	0	0	0	0	14	0	0	1	14	0	5047	79715	101283	5367277	100
	30051	Procare Home Health Services	Greene	0	0	0	0	0	0	0	0	0	0	0	0	50	0	50	0	18949	17836	216274	8518176	100
	33433	Maxim Healthcare Services	Hamilton	0	0	0	0	0	0	0	0	22	49	42	31	40	84	42	33	113	515	176315	8004439	100
	40075	Henry County Medical Center Home Health	Henry	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	417	8613	0	839108	100
	60024	NHC Homecare	Maury	0	0	0	0	0	0	0	0	0	0	0	0	200	0	0	0	2897	76067	0	14200206	100
	79526	Still Waters Home Health Agency	Shelby	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	701	17129	22970	1283276	100
	79558	Coram CVS/Specialty Infusion Service	Shelby	0	0	0	0	0	0	0	0	0	0	0		145	188	118	770	35	263	958	80905	100
	19744	Pentac Health, Inc.	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	46	221	910	44171	100

Supplemental #2
June 15, 2018
11:27 A.M.

Supplemental #2
June 15, 2018
11:27 A.M.

	Facility ID Info			Patients Served and Gross Revenue By Revenue Source – Medicare				Patients Served and Gross Revenue By Revenue Source – Medicare Advantage				Patients Served and Gross Revenue By Revenue Source – UHC Community Plan (Medicaid/Tenncare				Patients Served and Gross Revenue By Revenue Source – Amerigroup (Medicaid/Tenncare)				Patients Served and Gross Revenue By Revenue Source – Blue Care (Medicaid/Tenncare)				Tenncare Select (Medicaid/Tenncare)				Tenncare, MCO (not specified)(Medicaid/Tenncare)			
				Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other	
	State ID	Facility Name	County	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours
	11303	Suncrest Home Health	Claiborne	0	0	0	0	0	0	0	0	0	45	0	0	0	0	0	0	0	194	0	0	0	0	0	0	0	0	0	0
	14024	Cumberland River Homecare	Clay	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	19324	Suncrest Home Health	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	43	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	19544	Home Care Solutions	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	19734	Coram CVS Specialty Infusion Services	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	6	0	0	0	0	0	0
	19994	Vanderbilt Affiliated Walgreens Services	Davidson	0	0	0	0	11	0	0	0	0	90	0	0	0	0	116	0	0	0	0	0	0	0	0	0	0	0	0	0
	21024	Suncrest Home Health	DeKalb	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0
	30051	Procare Home Health Services	Greene	50	0	50	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	33433	Maxim Healthcare Services	Hamilton	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40075	Henry County Medical Center Home Health	Henry	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	60024	NHC Homecare	Maury	200		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0
	79526	Still Waters Home Health Agency	Shelby	0	0	1	1	0	0	0	0	0	0	0	0	136	136	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	79556	Coram CVS/Specialty Infusion Service	Shelby	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	19744	Pantec Health, Inc.	Davidson	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Supplemental #2
June 15, 2018
11:27 A.M.

Facility ID Info			Patients Served and Gross Revenue By Revenue Source - Other State Medicaid (Medicaid/TennCare)				Patients Served and Gross Revenue By Revenue Source - CoverKids (Medicaid/Tenncare)				Patients Served and Gross Revenue By Revenue Source -- TRICARE				Patients Served and Gross Revenue By Revenue Source -- Commercial				Patients Served and Gross Revenue By Revenue Source -- Self Pay				Patients Served and Gross Revenue By Revenue Source -- Home and Community Based Waiver Programs				Patients Served and Gross Revenue By Revenue Source -- TN Commission on Aging and Disability			
			Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other	
State ID	Facility Name	County	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours
13032	Suncrest Home Health	Claiborne	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14078	Cumberland River Homecare	Clay	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18324	Suncrest Home Health	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19544	Home Care Solutions	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19734	Coram CVS Speciality Infusion Services	Davidson	0	0	0	0	0	0	0	0	52	276	3	4	240	1228	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19994	Vanderbilt Affiliated Walgreens Services	Davidson	0	0	0	0	0	0	0	0	0	0	40	0	0	0	430	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
21024	Suncrest Home Health	DeKalb	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
30051	Procare Home Health Services	Greene	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
33433	Maxim Healthcare Services	Hamilton	0		0	0	0	0	0	0		0	0	0	0	0	0	0	16	6	0	0	0	0	0	0	0	0	0	0	0	0
40075	Henry County Medical Center Home Health	Henry	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
60024	NHC Homecare	Maury	0	0	0		0	0	0	0	0		0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
79526	Still Waters Home Health Agency	Shelby	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
79556	Coram CVS/Speciality Infusion Service	Shelby	0	0	0	0	0		0		40	92	10	14	105	98	108	756	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19744	Pentec Health, Inc.	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0

Supplemental #2
June 15, 2018
11:27 A.M.

Facility ID Info			Patients Served and Gross Revenue By Revenue Source -- Charity Care				Patients Served and Gross Revenue By Revenue Source -- Federal Department of Labor (EEOICP)				Patients Served and Gross Revenue By Revenue Source -- Other				Patients Served and Gross Revenue By Revenue Source -- Total All Revenue Sources								
			Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Infusion Therapy - Pain Management		Infusion Therapy - Other		Totals				
State ID	Facility Name	County	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Patients	Visits	Hours	Gross Revenue	Percentage of total
13054	Suncrest Home Health	Claiborne	0	0	0	0	0	0	0	0	0	203	0	0	0	443	0	0	1937	35510	59404	5715923	100
14024	Cumberland River Homecare	Clay	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	390	10288	105445	6590015	100
19324	Suncrest Home Health	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	43	0	0	5437	72976	78870	9264856	100
19544	Home Care Solutions	Davidson	0	0	0	0	0	0	0	0	14	9	0	0	14	9	0	0	1475	43618	38570	6515442	100
19734	Coram CVS Specialty Infusion Services	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	294	1510	3	4	35	297	1514	70915	100
19994	Vanderbilt Affiliated Walgreens Services	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1505	0	296	1505	0	195644	100
21024	Suncrest Home Health	DeKalb	0	0	0	0	0	0	0	0	0	0	14	0	0	1	14	0	5047	79715	101263	5367277	100
30051	Procare Home Health Services	Greene	0	0	0	0	0	0	0	0	0	0	0	0	50	0	50	0	18949	17836	216274	6518176	100
33433	Maxim Healthcare Services	Hamilton	0	0	0	0	0	0	0	0	22	49	42	31	40	84	42	33	113	515	176315	6004438	100
40075	Henry County Medical Center Home Health	Henry	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	417	8613	0	839108	100
60024	NHC Homecare	Maury	0	0	0	0	0	0	0	0	0	0	0	0	200	0	0	0	2897	76067	0	14200206	100
79526	Still Waters Home Health Agency	Shelby	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	701	17129	22970	1283276	100
79556	Coram CVS/Specialty Infusion Service	Shelby	0	0	0	0	0	0	0	0	0	0	0		145	186	118	770	35	263	958	80905	100
19744	Pantec Health, Inc.	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	46	221	910	44171	100

Supplemental #2
June 15, 2018
11:27 A.M.

Supplemental Response:

10. Section B. Need, Item 1 (Specific Criteria: Home Health Services) (5) Current Service Area Utilization

Supplement Attachment 13

Certificate of Need Home Health Projects-Approved but Unimplemented

County	Entity	CON Number	Status	Description	Cost	Date
				2017		
Davidson	Walgreens Infusion and Respiratory Services, LLC d/b/a Vanderbilt HC/Walgreens IV &RT Servics	CN1612-040	A	Relocation of its home health agency's principle office of 500 Wilson Pike Circle, Suite 115, Brentwood, TN to 624 Grassmere Park Drive. Suite 22, Nashville, TN.	$3,867,636.77	2/22/2017
Jefferson	Tennessee Nursing Services of Morristown, Inc. d/b/a SunCrest Home Health	CN1612-042	A	Relocation of its home health agency's principal office from Claiborne County to Jefferson County.	$306,432.00	4/26/2017
Shelby	AxelaCare Health Solutions, LLC East Tennessee	CN1702-008	A	Expand by 34 counties in East TN for home health limited to IG pharmaceuticals and related nursing services. (Counties east of and including Scott, Morgan, Cumberland, Bledsoe, Sequatchie, and Marion)	$70,000.00	8/23/2017
Shelby	AxelaCare Health Solutions, LLC Middle Tennessee	CN1702-009	A	Expand by 40 counties in Middle TN for home health limited to IG pharmaceuticals and related nursing services. (Counties between & including TN River and Fentress, Overton, Putnam, White, Van Buren, Grundy, and Franklin)	$70,000.00	8/23/2017
Shelby	Premier Health Care LLC	CN1608-027	D	Establish home health agency for private duty care in Fayette, Haywood, Madison, Shelby and Tipton counties.	$50,000.00	2/22/2017

County	Entity	CON Number	Status	Description	Cost	Date
2016						
Davidson	Maxlife at Home of Tennessee LLC./ d/b/a Careall Home Care Services	CN1608-029	A	Relocating home health agency from 900 Nashville Highway Columbia, Maury County TN, to 4015 Travis Drive Suite 103, Nashville, Davidson County TN. Surrendering Maury, Giles, Lawerence, Wayne, Lewis and Hickman Counties.	$67,054.88	10/26/2016
Davidson	VIP Home Nursing/D/b/a Careall Home Care Services	CN1608-028	A	Home Health agency adding Maury, Giles, Lawerence, Wayne, Lewis and Hickman Counties. Acquired by the surrender of the same six counties from another Office. No new services.	$21,000.00	10/26/2016
Shelby	AxelaCare Health Solutions LLC.	CN1606-022	A	To establish a home health agency to be exclusively limited to providing home infusion of immune globulin pharmaceuticals. (21 counties west of TN River)	$69,628.00	10/26/2016
Shelby	Prestige Home Care/Angelic Visits, LLC	CN1602-007	W	Establish a home health care agency in Shelby and Tipton counties.	$4,000.00	6/22/2016
Shelby	Tender Love Care	CN1605-000	Void	Establish a home health agency for Shelby and Tipton Counties.	$248,000.00	8/24/2016

County	Entity	CON Number	Status	Description	Cost	Date
Williamson	Maxim Healthcare Services, Inc.	CN1606-023	A	Relocation of home health agency from 2416 21st Ave South, Nashville, TN 37212 to 115 East Park Drive, Suite 200, Brentwood, TN 37027.	$3,201,828.00	8/24/2016
2015						
Anderson	The Home Option by Harden Healthcare	CN1501-001	A	Initiation of home health services in Blount Campbell Claiborne Grainger Monroe Morgan Roane & Scott by trnasfer from Gentiva Cert. Healthcare (sister agency) to HOHH's current licensed counties of Anderson Jefferson Knox Loudon Sevier & Union.	$38,000.00	3/25/2015
Morgan	Hero Healthcare	CN1504-012	W	To establish a Home Health Agency in Anderson and Morgan Counties, restricted to provide home health care to one specific patient in Anderson County.	$29,680.00	8/26/2015
Morgan	Hero Healthcare, LLC	CN1503-0	Void	To establish a home care organization and initiation of home health services restricted to provide services to a single patient in Anderson County.	$28,000.00	6/24/2015
Roane	CAMM Care LLC d/b/a Patriot Homecare	CN1506-023	D	To provide licensed Home Health services in Anderson, Knox, Meigs, Morgan and Roane coutnies.. The principle office will be located at 514 Devonia St, Harrima, Roane County, Tennessee 37748	$41,080.00	9/23/2015

Supplemental Response:

11. Section B. Need, Item 1 (Specific Criteria: Home Health Servies((9) Proposed Charges

Supplemental Attachment 14

Fee Comparison (Jar Data)

Supplemental #2

Fee Comparison - JAR Data

	Medicare Certified Home Care Organization								Private Duty Company			
	Charge Per Visit - Direct Only		Charge Per Visit - Direct & Indirect		Charge Per Episode of Care - Direct Only		Charge Per Episode of Care - Direct & Indirect		Average Charge Per Visit		Average Charge Per Hour	
	Infusion Therapy - Pain Management	Infusion Therapy - Other	Infusion Therapy - Pain Management	Infusion Therapy - Other	Infusion Therapy - Pain Management	Infusion Therapy - Other	Infusion Therapy - Pain Management	Infusion Therapy - Other	Infusion Therapy - Pain Management	Infusion Therapy - Other	Infusion Therapy - Pain Management	Infusion Therapy - Other
Cumberland River Homecare (14024)	0	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Suncrest Home Health (19824)	145	0	145	0	145	0	145	0	150	0	75	0
Suncrest Home Health (19082)	198	198	198	198	198	198	198	198	n/a	n/a	75	75
Suncrest Homes Health (21024)	0	0	0	0	0	0	0	0	0	0	0	0
Home Care Solutions (19544)	0	0	0	0	0	0	0	0	n/a	n/a	n/a	n/a
Gamm CVS Specialty Infusion Services (19734)	1	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Vanderbilt Affiliated Walgreens Services (19984)		120										
Pulcare Home Health Services (90051)	175	175	175	175	175	175	175	175	0	0	0	0
Nikdm Healthcare Services (93499)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	120	n/a	30
Maury County Medical Center Home Health (40075)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
NHC Homecare (60024)	0	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Still Waters Home Health Agency (79526)	110	110	110	110	110	110	110	110	n/a	n/a	n/a	n/a
Coram CVS/Specialty Infusion Service (79556)	1	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

	Charge Per Visit - Direct Only	Charge Per Visit - Direct & Indirect	Charge Per Episode of Care - Direct Only	Charge Per Episode of Care - Direct & Indirect	Average Charge Per Visit	Average Charge Per Hour
*Pentec Health	275	275				

*It is our assumption that the charge per visit for skilled nursing applies to Pentec's intrathecal infusion business.

	Proposed Charges
Implanted Pump Management, LLC	200
* Proposed in Certificate of Need	

Supplemental #2
June 15, 2018
11:27 A.M.

Supplemental Response:

13. Section B, Need, Item C

Supplemental Attachment 15

Projected Utilization Chart

AIS Historical Chart

Nursing – 2019 Projected Utilization By Patient Count

Based on 2017 Pharmacy Utilization Data

Section B, Need, Item C

Service Area Counties	Projected Utilization	% of Total Procedures
Anderson	1	0.99%
Bedford	1	0.99%
Benton		
Bledsoe		
Blount	1	0.99%
Bradley	1	0.99%
Campbell	1	0.99%
Cannon	0	
Carroll		
Carter	1	0.99%
Cheatham	1	0.99%
Chester		
Claiborne		
Clay		
Cocke	1	0.99%
Coffee	1	0.99%
Crockett		
Cumberland		
Davidson	12	11.88%
Decatur		
DeKalb	1	0.99%
Dickson	1	0.99%
Dyer		
Fayette	1	0.99%
Fentress		
Franklin		
Gibson		
Giles		
Grainger	1	0.99%
Greene	1	0.99%
Grundy		
Hamblen	3	2.97%
Hamilton		

Hancock		
Hardeman	1	0.99%
Hardin		
Hawkins	1	0.99%
Haywood	1	0.99%
Henderson		
Henry		
Hickman	1	0.99%
Houston		
Humphreys		
Jackson		
Jefferson	2	1.98%
Johnson	1	0.99%
Knox	6	5.94%
Lake		
Lauderdale	1	0.99%
Lawrence		
Lewis	1	0.99%
Lincoln		
Loudon		
Macon	1	0.99%
Madison	2	1.98%
Marion	1	0.99%
Marshall	1	0.99%
Maury	1	0.99%
McMinn	1	0.99%
McNairy	1	0.99%
Meigs	1	0.99%
Monroe		
Montgomery	3	2.97%
Moore		
Morgan		
Obion		
Overton		
Perry		
Pickett		
Polk		0.00%
Putnam		
Rhea		
Roane		0.00%
Robertson	3	2.97%

Rutherford	5	4.95%
Scott		
Sequatchie		
Sevier		
Shelby	7	6.93%
Smith		
Stewart		
Sullivan	3	2.97%
Sumner	6	5.94%
Tipton		
Trousdale		
Unicoi		
Union		
Van Buren		
Warren	1	0.99%
Washington	13	12.87%
Wayne		
Weakley		
White		
Williamson	3	2.97%
Wilson	4	3.96%
Total	101	100.00%

Projected utilization of nursing services is based on 2017 pharmaceutical services usage. ANS anticipates serving 103 patients in 2019 with an average utilization of approximately three visits per patient. While the average patient receives 5.5 refills per year, our projected utilization takes into consideration rolling/staggered enrollment of patients onto our home care services program in Year 1.

Supplemental #2
June 15, 2018
11:27 A.M.

Nursing – 2020 Projected Utilization By Patient Count

Based on 2017 Pharmacy Utilization Data & Projected Growth

Section B, Need, Item C

Service Area Counties	Projected Utilization	% of Total Procedures
Anderson	1	0.89%
Bedford	1	0.89%
Benton		
Bledsoe		
Blount	1	0.89%
Bradley	1	0.89%
Campbell	1	0.89%
Cannon*	1	0.89%
Carroll		
Carter	1	0.89%
Cheatham	1	0.89%
Chester		
Claiborne		
Clay		
Cocke	1	0.89%
Coffee	1	0.89%
Crockett		
Cumberland		
Davidson*	15	13.39%
Decatur		
DeKalb	1	0.89%
Dickson*	2	1.79%
Dyer		
Fayette	1	0.89%
Fentress		
Franklin		
Gibson		
Giles		
Grainger	1	0.89%
Greene	1	0.99%
Grundy		
Hamblen	3	2.68%
Hamilton		

Hancock		
Hardeman	1	0.89%
Hardin		
Hawkins	1	0.89%
Haywood	1	0.89%
Henderson		
Henry		
Hickman	1	0.89%
Houston		
Humphreys		
Jackson		
Jefferson	2	1.79%
Johnson	1	0.89%
Knox	6	5.36%
Lake		
Lauderdale	1	0.89%
Lawrence		
Lewis	1	0.89%
Lincoln		
Loudon		
Macon	1	0.89%
Madison	2	1.79%
Marion	1	0.89%
Marshall	1	0.89%
Maury	1	0.89%
McMinn	1	0.89%
McNairy	1	0.89%
Meigs	1	0.89%
Monroe		
Montgomery	3	2.68%
Moore		
Morgan		
Obion		
Overton		
Perry		
Pickett		
Polk		
Putnam		
Rhea		
Roane		
Robertson	3	2.68%

Supplemental #2
June 15, 2018
11:27 A.M.

Rutherford	5	4.46%
Scott		
Sequatchie		
Sevier		
Shelby*	9	8.04%
Smith		
Stewart		
Sullivan	3	2.68%
Sumner*	7	6.25%
Tipton		
Trousdale		
Unicoi		
Union		
Van Buren		
Warren	1	0.89%
Washington	15	13.39%
Wayne		
Weakley		
White		
Williamson*	4	3.57%
Wilson	4	3.57%
Total	112	100.00%

2017 – Pharmacy – Historical Utilization By Patient Count

Section B, Need, Item C

Service Area Counties	Number of Patients	% of Total Procedures
Anderson	11	1.13%
Bedford	10	1.03%
Benton	4	0.41%
Bledsoe	0	0.00%
Blount	12	1.23%
Bradley	9	0.92%
Campbell	2	0.21%
Cannon	3	0.31%
Carroll	2	0.21%
Carter	6	0.62%
Cheatham	8	0.82%
Chester	2	0.21%
Claiborne	4	0.41%
Clay	1	0.10%
Cocke	8	0.82%
Coffee	15	1.54%
Crockett	3	0.31%
Cumberland	9	0.92%
Davidson	62	6.37%
Decatur	4	0.41%
DeKalb	10	1.03%
Dickson	4	0.41%
Dyer	5	0.51%
Fayette	11	1.13%
Fentress	0	0.00%
Franklin	13	1.33%
Gibson	10	1.03%
Giles	7	0.72%
Grainger	5	0.51%
Greene[1]	9	0.92%
Grundy	2	0.21%
Hamblen[2]	14	1.44%

[1] County includes one patient from Limestone Community
[2] County includes patient(s) from Umatilla Community

Hamilton	26	2.67%
Hancock	1	0.10%
Hardeman	6	0.62%
Hardin	1	0.10%
Hawkins	5	0.51%
Haywood	2	0.21%
Henderson	5	0.51%
Henry	2	0.21%
Hickman	4	0.41%
Houston	1	0.10%
Humphreys	1	0.10%
Jackson	0	0.00%
Jefferson	16	1.64%
Johnson	5	0.51%
Knox	62	6.37%
Lake	2	0.21%
Lauderdale	6	0.62%
Lawrence	16	1.64%
Lewis	2	0.21%
Lincoln	13	1.33%
Loudon	11	1.13%
Macon	7	0.72%
Madison	20	2.05%
Marion	1	0.10%
Marshall	7	0.72%
Maury	13	1.33%
McMinn	4	0.41%
McNairy	3	0.31%
Meigs	2	0.21%
Monroe	7	0.72%
Montgomery	33	3.39%
Moore	1	0.10%
Morgan	4	0.41%
Obion		0.00%
Overton	3	0.31%
Perry	1	0.10%
Pickett	0	0.00%
Polk	3	0.31%
Putnam	13	1.33%
Rhea	2	0.21%
Roane	10	1.03%

Robertson	25	2.57%
Rutherford	52	5.34%
Scott	4	0.41%
Sequatchie	1	0.10%
Sevier	26	2.67%
Shelby	73	7.49%
Smith	1	0.10%
Stewart	5	0.51%
Sullivan	30	3.08%
Sumner	62	6.37%
Tipton	5	0.51%
Trousdale	1	0.10%
Unicoi	6	0.62%
Union	4	0.41%
Van Buren	2	0.21%
Warren	4	0.41%
Washington	32	3.29%
Wayne	1	0.21%
Weakley	2	0.21%
White	5	0.51%
Williamson	28	2.87%
Wilson	19	1.95%
Total	975	100.00%

2017 – Pharmacy – Historical Utilization By Syringe Count

Section B, Need, Item C

Service Area Counties	Historical Utilization - County Residents	% of Total Procedures
Anderson	38	0.88%
Bedford	41	0.95%
Benton	18	0.42%
Bledsoe	0	0.00%
Blount	56	1.30%
Bradley	21	0.49%
Campbell	10	0.23%
Cannon	13	0.30%
Carroll	7	0.16%
Carter	13	0.30%
Cheatham	44	1.02%
Chester	11	0.25%
Claiborne	15	0.35%
Clay	7	0.16%
Cocke	44	1.02%
Coffee	92	2.13%
Crockett	15	0.35%
Cumberland	40	0.93%
Davidson	285	6.60%
Decatur	24	0.56%
DeKalb	44	1.02%
Dickson	19	0.44%
Dyer	24	0.56%
Fayette	41	0.95%
Fentress	0	0.00%
Franklin	67	1.55%
Gibson	51	1.18%
Giles	22	0.51%
Grainger	30	0.69%
Greene[3]	47	1.09%
Grundy	5	0.12%

[3] County includes one patient from Limestone Community

Hamblen[4]	109	2.52%
Hamilton	91	2.11%
Hancock	6	0.14%
Hardeman	26	0.60%
Hardin	5	0.12%
Hawkins	19	0.44%
Haywood	8	0.19%
Henderson	20	0.46%
Henry	2	0.05%
Hickman	22	0.51%
Houston	8	0.19%
Humphreys	6	0.14%
Jackson	0	0.00%
Jefferson	71	1.64%
Johnson	13	0.30%
Knox	258	5.97%
Lake	9	0.21%
Lauderdale	33	0.76%
Lawrence	41	0.95%
Lewis	7	0.16%
Lincoln	67	1.55%
Loudon	35	0.81%
Macon	36	0.83%
Madison	101	2.34%
Marion	2	0.05%
Marshall	11	0.25%
Maury	38	0.88%
McMinn	13	0.30%
McNairy	18	0.42%
Meigs	5	0.12%
Monroe	39	0.90%
Montgomery	182	4.21%
Moore	5	0.12%
Morgan	12	0.28%
Obion	23	0.53%
Overton	16	0.37%
Perry	4	0.09%
Pickett	0	0.00%
Polk	7	0.16%
Putnam	72	1.67%

[4] County includes patient(s) from Umatilla Community

Supplemental #2
June 15, 2018
11:27 A.M.

Rhea	2	0.05%
Roane	44	1.02%
Robertson	105	2.43%
Rutherford	261	6.04%
Scott	16	0.37%
Sequatchie	1	0.02%
Sevier	111	2.57%
Shelby	275	6.37%
Smith	5	0.12%
Stewart	26	0.60%
Sullivan	126	2.92%
Sumner	295	6.83%
Tipton	24	0.56%
Trousdale	7	0.16%
Unicoi	25	0.58%
Union	11	0.25%
Van Buren	10	0.23%
Warren	19	0.44%
Washington	119	2.76%
Wayne	2	0.05%
Weakley	5	0.12%
White	20	0.46%
Williamson	126	2.92%
Wilson	100	2.32%
Total	4319	100.00%

Supplemental #2
June 15, 2018
11:27 A.M.

Supplemental Response:

14. Section B, Need, Item D.1

Supplemental Attachment 16

Revised Demographic Table

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Anderson	78,387	79,061	0.9	62,000	62,772	1.2	20.60	43.3	44,241	12,747	17.2%	7,849	10.01%
Bedford	50,860	51,961	2.2	37,735	38,657	2.4	25.60	36.9	43,819	7,423	16.3%	5,055	9.94%
Benton	16,711	16,741	0.2	13,666	13,764	0.7	17.78	46.6	33,611	3,614	22.6%	2,109	12.62%
Bledsoe	13,394	13,481	0.6	10,825	10,935	1.0	18.88	43.0	38,535	3,050	23.7%	1,524	11.38%
Blount	136,505	139,725	2.4	108,596	111,741	2.9	20.04	43.0	49,532	16,793	13.6%	10,487	7.68%
Bradley	107,651	109,706	1.9	83,908	85,865	2.3	21.73	39.3	43,721	18,291	18.4%	10,368	9.63%
Campbell	41,654	41,787	0.3	33,167	33,459	0.9	19.93	43.5	33,628	8,821	22.4%	6,911	16.59%
Cannon	14,658	14,838	1.2	11,739	11,956	1.8	19.42	42.1	43,654	2,208	16.2%	1,569	10.70%
Carroll	28,753	28,782	0.1	22,648	22,726	0.3	21.05	42.9	36,212	5,441	19.8%	6,052	21.05%
Carter	60,154	60,733	1.0	48,587	49,243	1.4	18.92	44.	33,177	13,110	23.9%	6,799	11.30%
Cheatham	41,269	41,692	1.0	32,140	32,717	1.8	21.52	40.2	53,179	5,061	12.9%	3,300	8.00%
Chester	18,633	18,978	1.9	14,720	15,098	2.6	20.48	37.1	42,376	2,911	17.9%	1,855	9.96%
Claiborne	34,263	34,713	1.3	27,727	28,307	2.1	18.45	42.3	33,428	6,771	22.3%	4,997	14.58%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Clay	7,876	7,785	0.0	6,337	6,350	0.2	18.43	47.4	28,147	1,904	24.8%	41	0.52%
Cocke	37,335	37,663	0.9	29,961	30,348	1.3	19.42	44.5	31,081	9,081	26.1%	5,918	15.85%
Coffee	56,909	57,865	1.7	43,634	44,534	2.1	23.03	40.1	45,456	8,437	15.9%	6,295	11.06%
Crockett	14,982	15,080	0.7	11,412	11,526	1.0	23.36	39.6	38,043	2,602	18.3%	1,757	11.73%
Cumberland	63,778	65,575	2.8	53,032	54,808	3.3	16.42	50.1	40,123	9,075	16.0%	6,091	9.55%
Davidson	698,061	714,756	2.4	528,965	539,109	1.9	24.57	34.2	50,484	114,238	17.7%	58,291	8.35%
Decatur	12,029	12,077	0.4	9,619	9,705	0.9	19.64	45.5	38,180	2,399	20.9%	1,489	12.38%
Dekalb	19,936	20,206	1.4	15,626	15,897	1.7	21.33	40.9	37,640	4,152	22.2%	2,495	12.52%
Dickson	54,959	56,210	2.3	42,109	43,271	2.8	23.01	40.0	47,137	8,019	15.9%	5,099	9.28%
Dyer	39,607	39,872	0.7	30,291	30,563	0.9	23.34	40.3	42,833	6,915	18.6%	5,063	12.78%
Fayette	46,608	48,510	4.1	36,749	38,496	4.8	20.64	44.4	55,972	5,774	15.0%	3,308	7.10%
Fentress	19,082	19,309	1.2	15,154	15,440	1.9	20.03	44.3	31,714	4,107	23.3%	3,221	16.88%
Franklin	42,395	42,681	0.7	33,998	34,523	1.5	19.11	41.9	44,837	6,397	16.2%	3,896	9.19%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Gibson	51,934	52,438	1.0	39,562	40,041	1.2	23.68	40.3	38,854	9,039	18.7%	6,233	12.00%
Giles	30,492	30,691	0.7	24,175	24,434	1.1	20.38	42.9	40,635	4,721	16.7%	3,165	10.38%
Grainger	24,244	24,577	1.4	19,320	19,677	1.8	19.94	44.2	37,522	4,578	20.2%	3,083	12.72%
Greene	73,620	74,656	1.4	59,408	60,547	1.9	18.90	44.0	36,711	12,373	18.6%	8,086	10.98%
Grundy	14,040	14,088	0.3	11,189	11,309	1.1	19.72	43.0	28,467	3,718	28.0%	2,428	17.29%
Hamblen	66,195	67,028	1.3	50,192	51,586	1.3	23.03	40.5	39,270	13,112	21.2%	6,975	10.54%
Hamilton	362,471	368,666	1.7	283,457	288,264	1.7	21.81	39.3	49,434	50,631	14.8%	30,468	8.41%
Hancock	6,981	7,007	0.4	5,594	5,641	0.8	19.45	44.3	27,973	1,757	27.3%	1,239	17.75%
Hardeman	27,284	27,278	0.0	22,014	22,135	0.5	18.85	39.9	33,566	5,285	23.7%	3,543	12.99%
Hardin	26,680	26,783	0.4	21,390	21,579	0.9	19.43	45.1	37,244	5,634	22.2%	3,816	14.30%
Hawkins	59,311	59,784	0.8	47,294	48,045	1.6	19.64	43.8	37,883	10,706	19.2%	6,880	11.60%
Haywood	18,274	18,128	-0.8	13,990	13,950	-0.3	23.04	40.4	35,094	3,744	21.0%	2,676	14.64%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Henderson	29,836	30,298	1.5	22,947	23,400	2.0	22.76	40.4	41,478	5,703	20.7%	3,551	11.90%
Henry	33,771	34,055	0.8	26,925	27,278	1.3	19.90	45.1	38,378	6,151	19.4%	3,842	11.38%
Hickman	26,876	27,363	1.8	21,460	21,965	2.4	19.72	40.4	37,546	5,181	22.9%	2,952	10.98%
Houston	9,014	9,157	1.6	7,055	7,210	2.2	21.26	43.5	40,680	1,675	20.9%	1,054	11.69%
Humphreys	19,090	19,185	0.5	15,033	15,217	1.2	20.68	41.7	40,995	3,308	18.5%	2,191	11.48%
Jackson	12,251	12,375	1.0	10,104	10,278	1.7	16.94	46.1	32,676	2,835	25.0%	1,501	12.25%
Jefferson	57,072	58,372	2.3	45,484	46,760	2.8	19.89	42.7	43,673	7,724	15.2%	6,026	10.56%
Johnson	18,952	19,112	0.8	15,734	15,968	1.5	16.45	44.8	30,180	4,313	26.9%	2,362	12.46%
Knox	477,780	488,993	2.3	372,202	381,171	2.4	22.05	37.3	50,366	70,612	16.2%	36,512	7.64%
Lake	8,441	8,579	1.6	7,234	7,392	2.2	13.84	40.7	29,893	1,413	29.2%	1,192	14.12%
Lauderdale	28,930	29,186	0.9	22,299	22,606	1.4	22.54	37.6	32,353	6,014	24.7%	3,789	13.10%
Lawrence	43,518	43,849	0.8	33,251	33,665	1.2	23.22	39.9	40,457	8,136	19.5%	5,216	11.99%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Lewis	12,912	13,072	1.2	10,160	10,371	2.1	20.66	43.6	36,920	2,384	20.4%	1,453	11.25%
Lincoln	35,104	35,469	1.0	27,369	27,797	1.6	21.63	42.9	41,038	6,123	18.5%	3,601	10.26%
Loudon	56,118	57,923	3.2	45,920	47,612	3.7	17.80	47.2	52,995	6,767	13.5%	4,109	7.32%
McMinn	55,100	55,724	1.1	43,501	44,132	1.5	20.80	42.9	38,661	10,012	19.5%	3,032	5.50%
McNairy	27,486	27,760	1.0	21,565	21,900	1.6	21.11	42.9	31,956	5,916	23.1%	11,249	40.93%
Macon	23,838	24,202	1.5	18,318	18,701	2.1	22.72	39.6	34,098	4,167	18.6%	3,032	12.72%
Madison	104,799	106,352	1.5	79,760	81,151	1.7	23.70	37.8	44,237	18,345	19.4%	11,249	10.73%
Marion	29,810	30,129	1.1	23,795	24,190	1.7	19.71	43.2	41,477	5,374	19.2%	3,466	11.63%
Marshall	33,885	34,648	2.3	26,086	26,833	2.9	22.56	39.6	44,900	4,655	15.1%	3,097	9.14%
Maury	90,666	92,944	2.5	69,267	71,249	2.9	23.34	39.1	49,597	12,413	14.7%	8,169	9.01%
Meigs	12,345	12,462	0.9	10,073	10,242	1.7	17.81	43.9	35,209	2,160	18.8%	1,577	12.77%
Monroe	49,048	50,062	2.1	38,893	29,979	2.8	40.12	43.1	37,054	8,575	19.2%	5,672	11.56%
Montgomery	211,602	221,620	4.7	149,533	156,218	4.5	29.51	30.3	51,528	28,232	15.2%	16,078	7.60%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Moore	6,923	7,056	1.9	5,604	5,754	2.7	18.45	46.5	49,496	644	10.4%	380	5.49%
Morgan	23,848	24,288	1.8	19,441	19,921	2.5	17.98	41.1	39,728	4,415	23.6%	2,280	9.56%
Obion	31,625	31,559	-0.2	24,919	24,940	0.1	20.97	42.5	38,933	6,399	21.1%	3,931	12.43%
Overton	23,885	24,291	1.7	18,772	19,179	2.2	21.04	42.6	35,065	4,340	20.0%	2,641	11.06%
Perry	8,362	8,466	1.2	6,626	6,742	1.8	20.36	43.3	31,274	2,216	28.6%	1,001	11.97%
Pickett	5,237	5,264	0.5	4,357	4,443	2.0	15.60	49.8	39,014	827	16.5%	593	11.32%
Polk	17,627	17,812	1.0	14,103	14,288	1.3	19.78	44.6	41,520	2,918	17.8%	2,124	12.05%
Putman	81,972	84,087	2.6	64,190	65,846	2.6	21.69	36.1	36,350	17,180	24.0%	8,520	10.39%
Rhea	34,582	35,216	1.8	26,899	27,610	2.6	21.60	40.3	38,355	7,160	22.9%	4,224	12.21%
Roane	55,990	56,301	0.6	45,510	45,977	1.0	18.33	46.3	42,299	8,449	16.2%	5,931	10.59%
Robertson	76,231	78,659	3.2	54,400	59,488	3.6	24.37	38.5	56,331	7,067	10.5%	5,650	7.41%
Rutherford	332,411	350,488	5.7	247,473	261,598	5.4	25.36	32.9	58,032	35,764	12.6%	21,094	6.35%
Scott	23,058	23,224	0.7	17,598	17,805	1.2	23.33	38.8	30,897	6,000	27.7%	3,931	17.05%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Sequatchie	16,399	16,943	3.3	12,946	13,442	3.8	20.66	42.5	46,541	2,328	16.1%	1,893	11.54%
Sevier	104,829	108,468	3.5	83,498	86,676	3.8	20.09	42.4	42,586	14,285	15.3%	9,115	8.70%
Shelby	970,212	981,022	1.1	720,465	728,710	1.1	25.72	35.1	46,854	196,471	21.4%	107,590	11.09%
Smith	20,534	20,833	2.2	16,001	16,348	1.5	21.53	41.2	44,272	3,050	16.2%	2,066	10.06%
Stewart	14,210	14,402	2.2	11,369	11,618	1.4	19.33	43.4	41,835	2,520	19.2%	1,558	10.96%
Sullivan	159,393	159,749	0.2	128,541	129,225	0.5	19.10	44.5	40,983	25,982	16.8%	17,100	10.73%
Sumner	184,532	190,261	3.1	141,250	146,486	3.7	23.01	39.5	58,972	16,543	9.7%	12,731	6.90%
Tipton	69,239	71,196	2.8	52,243	54,039	3.4	24.10	37.3	54,650	8,378	13.8%	6,030	8.71%
Trousdale	8,564	8,739	2.0	6,661	6,829	2.5	21.86	39.0	47,667	1,043	13.3%	986	11.51%
Unicoi	19,003	19,150	0.8	15,430	15,615	1.2	18.46	45.6	35,390	3,687	21.0%	2,185	11.50%
Union	20,124	20,320	1.0	15,654	15,892	1.5	21.79	41.5	38,540	4,420	23.5%	2,541	12.63%
Van Buren	5,668	5,686	0.3	4,654	4,694	0.9	17.45	45.8	42,813	1,058	19.1%	691	12.19%
Warren	41,167	41,446	0.7	31,588	31,909	1.1	23.01	39.9	36,245	8,158	20.7%	5,403	13.12%

Demographic Variable/Geographic Area	Department of Health/Health Statistics**							Bureau of the Census*				TennCare-	
	Total Population-Current Year-2018	Total Population-Projected Year-2020	Total Population-% Change	*Target Population-Current Year	*Target Population-Project Year	*Target Population-% Change	Target Population Projected Year as % of Total	Median Age-2016	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total Population
Washington	137,400	140,905	2.6	110,132	113,097	2.7	19.74	39.7	44,444	20,810	17.1%	12,214	8.89%
Wayne	17,551	17,642	0.5	14,491	14,667	1.2	16.86	41.9	34,008	2,796	18.9%	1,673	9.53%
Weakley	36,300	36,360	0.2	29,283	29,385	0.3	19.18	37.5	38,040	5,962	19.1%	3,543	9.76%
White	28,037	28,541	1.8	22,286	22,815	2.4	20.06	43.5	35,989	4,662	18.1%	3,579	12.77%
Williamson	225,526	241,597	7.1	168,033	182,015	8.3	24.66	39.0	100,140	10,547	5.2%	5,399	2.39%
Wilson	133,865	138,561	3.5	103,160	107,612	4.3	22.33	40.3	63,426	11,266	9.1%	8,474	6.33%
Service Area Total	6,960,524	7,112,424	2.2	5,367,165	5,496,968	2.4	22.71	38.6	48,547	1,100,169	17.2%		
State of TN Total	6,960,524	7,112,424	2.2	5,367,165	5,496,968	2.4	22.71	38.6	48,547	1,100,169	17.2%		

Acknowledgement: Population data was provided by the Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics.

*2016 factfinder.census.gov
Source: U.S. Census Bureau, 2012-2016 American Community Survey
**2017 Revised UTCBER Population Projections Series
Source: The University of Tennessee Center for Business and Economic Research Population Data Files, Reassembled by the Tennessee Department of Health, Division of Policy, Planning and Assessment.
Note: These data will not match the University of Tennessee Data exactly due to rounding.

Supplemental Response:

15. Section B, Need Item E

Supplemental Attachment 17

Existing Similar Healthcare Provider Utilization

Section B, Need, Item E - 2017 Existing Similar Healthcare Provider Utilization

Facility ID Info			2017 - Total All Revenue Sources										
			Skilled Nursing Care		Infusion Therapy - Pain Management		Infusion Therapy - Other		Totals				
State ID	Facility Name	Base County	Visits	Hours	Visits	Hours	Visits	Hours	Patients	Visits	Hours	Gross Revenue	% of total
13032	Suncrest Home Health	Claiborne	17475	18208	0	443	0	0	1937	35510	59404	5715923	100
14024	Cumberland River Homecare	Clay	2616	15968	1	0	1	0	390	10288	105445	6590015	100
19324	Suncrest Home Health	Davidson	30548	28382	0	43	0	0	5437	72976	76970	9264856	100
19544	Home Care Solutions	Davidson	17245	16731	14	9	0	0	1475	43618	38570	6516442	100
19734	Coram CVS Speciality Infusion Services	Davidson	0	0	294	1510	3	4	35	297	1514	70915	100
19744	Pentec Health	Davidson	221	910	0	0	0	0	46	221	910	44171	100
19994	Vanderbilt Affiliated Walgreens Services	Davidson					1505		296	1505	0	195644	100
21024	Suncrest Home Health	DeKalb	32282	26060	0	1	14	0	5047	79715	101263	5367277	100
30051	Procare Home Health Services	Greene	2086	169823	50	0	50	0	18949	17836	216274	6518176	100
33433	Maxim Healthcare Services	Hamilton	433	145611	40	84	42	33	113	515	176315	6004439	100
40075	Henry County Medical Center Home Health	Henry	3843	0	8	0	0	0	417	8613	0	839108	100
60024	NHC Homecare	Maury	43598	0	200	0	0	0	2897	76067	0	14200206	100
79526	Still Waters Home Health Agency	Shelby	4298	4654	0	0	2	2	701	17129	22970	1283276	100
79556	Coram CVS/Speciality Infusion Service	Shelby	0	0	145	188	118	770	35	263	958	80905	100

Section B, Need, Item E - 2016 Existing Similar Healthcare Provider Utilization					
Facility ID Info					
State ID	Facility Name	Base County	Skilled Nursing Care Visits	Skilled Nursing Care Hours	Total Patients
13032	Suncrest Home Health	Claiborne	10,897	11,557	1,902
14024	Cumberland River Homecare	Clay	2,814	88,784	372
19324	Suncrest Home Health	Davidson	60,811	38,901	7,156
19544	Home Care Solutions	Davidson	23,636	355	1,597
19734	Coram CVS Speciality Infusion Services	Davidson	328	536	
19744	Pentec Health	Davidson	72	0	46
19994	Vanderbilt Affiliated Walgreens Services	Davidson	data not available		
21024	Suncrest Home Health	DeKalb	43,604	66,252	3,412
30051	Procare Home Health Services	Greene	1,714	179,574	196,684
33433	Maxim Healthcare Services	Hamilton	1,178	146,923	178
40075	Henry County Medical Center Home Health	Henry	2,697	0	427
60024	NHC Homecare	Maury	42,461	0	2,862
79526	Still Waters Home Health Agency	Shelby	1,574	99	116
79556	Coram CVS/Speciality Infusion Service	Shelby	75	142	21

Section B, Need, Item E - 2015 Existing Similar Healthcare Provider Utilization					
Facility ID Info					
State ID	Facility Name	Base County	Skilled Nursing Care Visits	Skilled Nursing Care Hours	Total Patients
13032	Suncrest Home Health	Claiborne	10,112	29,528	1,291
14024	Cumberland River Homecare	Clay	2,406	77,114	354
19324	Suncrest Home Health	Davidson	32,088	61,236	4,502
19544	Home Care Solutions	Davidson	32,110	475	1,813
19734	Coram CVS Speciality Infusion Services	Davidson	241	872	36
19744	Pentec Health	Davidson	data not available		
19994	Vanderbilt Affiliated Walgreens Services	Davidson	data not available		
21024	Suncrest Home Health	DeKalb	39,842	0	2,713
30051	Procare Home Health Services	Greene	1,145	155,951	199,233
33433	Maxim Healthcare Services	Hamilton	641	157,534	133
40075	Henry County Medical Center Home Health	Henry	2,796	0	428
60024	NHC Homecare	Maury	39,503	0	2,559
79526	Still Waters Home Health Agency	Shelby	1,533	0	0
79556	Coram CVS/Speciality Infusion Service	Shelby	8	11	4

Facility ID Info			Patients Served and Gross Revenue By Revenue Source – Medicare				Patients Served and Gross Revenue By Revenue Source – Medicare Advantage				Patients Served and Gross Revenue By Revenue Source – UHC Community Plan (Medicaid/Tenncare				Patients Served and Gross Revenue By Revenue Source – Amerigroup (Medicaid/Tenncare)				Patients Served and Gross Revenue By Revenue Source – Blue Care (Medicaid/Tenncare)				Tenncare Select (Medicaid/Tenncare)				Tenncare, MCO (not specified)(Medicaid/Tenncare)			
			Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other	
	State ID	Facility Name	County	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours
	13032	Suncrest Home Health	Claiborne	0	0	0	0	0	0	0	0	0	45	0	0	0	0	0	0	0	194	0	0	0	0	0	0	0	0	0	0
	14024	Cumberland River Homecare	Clay	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	19324	Suncrest Home Health	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	43	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	19544	Home Care Solutions	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	19734	Coram CVS Specialty Infusion Services	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	6	0	0	0	0	0	0
	19994	Vanderbilt Affiliated Walgreens Services	Davidson	0	0	0	0	11	0	0	0	0	90	0	0	0	0	116	0	0	0	0	0	0	0	0	0	0	0	0	0
	21024	Suncrest Home Health	DeKalb	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0
	30051	Procare Home Health Services	Greene	50	0	50	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	33433	Maxim Healthcare Services	Hamilton	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40075	Henry County Medical Center Home Health	Henry	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	60024	NHC Homecare	Maury	200		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0
	79526	Still Waters Home Health Agency	Shelby	0	0	1	1	0	0	0	0	0	0	0	0	138	136	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	79556	Coram CVS/Specialty Infusion Service	Shelby	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	19744	Pentac Health, Inc.	Davidson	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Supplemental #2
June 15, 2018
11:27 A.M.

Facility ID Info			Patients Served and Gross Revenue By Revenue Source - Other State Medicaid (Medicaid/TennCare)				Patients Served and Gross Revenue By Revenue Source - CoverKids (Medicaid/Tenncare)				Patients Served and Gross Revenue By Revenue Source – TRICARE				Patients Served and Gross Revenue By Revenue Source – Commercial				Patients Served and Gross Revenue By Revenue Source – Self Pay				Patients Served and Gross Revenue By Revenue Source – Home and Community Based Waiver Programs				Patients Served and Gross Revenue By Revenue Source – TN Commission on Aging and Disability			
			Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other	
State ID	Facility Name	County	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours
13032	Suncrest Home Health	Claiborne	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14024	Cumberland River Homecare	Clay	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19324	Suncrest Home Health	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19544	Home Care Solutions	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19734	Coram CVS Specialty Infusion Services	Davidson	0	0	0	0	0	0	0	0	52	276	3	4	240	1226	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19994	Vanderbilt Affiliated Walgreens Services	Davidson	0	0	0	0	0	0	0	0	0	0	40	0	0	0	430	0	0	0	1	0	0	0	0	0	0	0	0	0
21024	Suncrest Home Health	DeKalb	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
30051	Procare Home Health Services	Greene	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
33433	Maxim Healthcare Services	Hamilton	0		0	0	0	0	0	0		0	0	0	0	0	0	0	18	6	0	0	0	0	0	0	0	0	0	0
40075	Henry County Medical Center Home Health	Henry	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
60024	NHC Homecare	Maury	0	0	0		0	0	0	0	0		0	0	0		0	0	0	0	0	0	0	0	0	0	0	0	0	0
79526	Still Waters Home Health Agency	Shelby	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0
79556	Coram CVS/Specialty Infusion Service	Shelby	0	0	0	0	0		0		40	92	10	14	105	98	108	756	0	0	0	0	0	0	0	0	0	0	0	0
19744	Pentec Health, Inc	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	0	0	0	0

Facility ID Info			Patients Served and Gross Revenue By Revenue Source – Charity Care				Patients Served and Gross Revenue By Revenue Source – Federal Department of Labor (EEOICP)				Patients Served and Gross Revenue By Revenue Source – Other				Patients Served and Gross Revenue By Revenue Source – Total All Revenue Sources									
			Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Infusion Therapy - Pain Management		Infusion Therapy Other		Totals					
State ID	Facility Name	County	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Visits	Hours	Patients	Visits	Hours	Gross Revenue	Percentage of total	
13032	Suncrest Home Health	Claiborne	0	0	0	0	0	0	0	0	0	203	0	0	0	443	0	0	1937	35510	59404	5715923	100	
14024	Cumberland River Homecare	Clay	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	390	10288	105445	8590015	100	
19324	Suncrest Home Health	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	43	0	0	5437	72976	76970	9264856	100	
19544	Home Care Solutions	Davidson	0	0	0	0	0	0	0	0	14	9	0	0	14	9	0	0	1475	43618	38570	8518442	100	
19734	Coram CVS Speciality Infusion Services	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	294	1510	3	4	35	297	1514	70915	100	
19994	Vanderbilt Affiliated Walgreen Services	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1505	0	296	1505	0	195644	100	
21024	Suncrest Home Health	DeKalb	0	0	0	0	0	0	0	0	0	0	14	0	0	1	14	0	5047	79715	101263	5367277	100	
30051	Procare Home Health Services	Greene	0	0	0	0	0	0	0	0	0	0	0	0	50	0	50	0	18949	17836	216274	8518176	100	
33433	Maxim Healthcare Services	Hamilton	0	0	0	0	0	0	0	0	22	49	42	31	40	84	42	33	113	515	176315	8004439	100	
40075	Henry County Medical Center Home Health	Henry	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	417	8813	0	839108	100	
80024	NHC Homecare	Maury	0	0	0	0	0	0	0	0	0	0	0	0	200	0	0	0	2897	76087	0	14200206	100	
79526	Still Waters Home Health Agency	Shelby	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	701	17129	22970	1283278	100	
79556	Coram CVS/Specialty Infusion Service	Shelby	0	0	0	0	0	0	0	0	0	0	0		145	188	118	770	35	283	958	80905	100	
19744	Pantac Health, Inc.	Davidson	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	48	221	910	44171	100	

Supplemental Response

Supplemental Attachment 18

Pharmacy Historical Utilization & Nursing Projected Utilization

2017 – Pharmacy – Historical Utilization By Patient Count

Section B, Need, Item F

Service Area Counties	Number of Patients	% of Total Procedures
Anderson	11	1.13%
Bedford	10	1.03%
Benton	4	0.41%
Bledsoe	0	0.00%
Blount	12	1.23%
Bradley	9	0.92%
Campbell	2	0.21%
Cannon	3	0.31%
Carroll	2	0.21%
Carter	6	0.62%
Cheatham	8	0.82%
Chester	2	0.21%
Claiborne	4	0.41%
Clay	1	0.10%
Cocke	8	0.82%
Coffee	15	1.54%
Crockett	3	0.31%
Cumberland	9	0.92%
Davidson	62	6.37%
Decatur	4	0.41%
DeKalb	10	1.03%
Dickson	4	0.41%
Dyer	5	0.51%
Fayette	11	1.13%
Fentress	0	0.00%
Franklin	13	1.33%
Gibson	10	1.03%
Giles	7	0.72%
Grainger	5	0.51%
Greene[1]	9	0.92%
Grundy	2	0.21%
Hamblen[2]	14	1.44%

[1] County includes one patient from Limestone Community

[2] County includes patient(s) from Umatilla Community

Supplemental #2
June 15, 2018
11:27 A.M.

Hamilton	26	2.67%
Hancock	1	0.10%
Hardeman	6	0.62%
Hardin	1	0.10%
Hawkins	5	0.51%
Haywood	2	0.21%
Henderson	5	0.51%
Henry	2	0.21%
Hickman	4	0.41%
Houston	1	0.10%
Humphreys	1	0.10%
Jackson	0	0.00%
Jefferson	16	1.64%
Johnson	5	0.51%
Knox	62	6.37%
Lake	2	0.21%
Lauderdale	6	0.62%
Lawrence	16	1.64%
Lewis	2	0.21%
Lincoln	13	1.33%
Loudon	11	1.13%
Macon	7	0.72%
Madison	20	2.05%
Marion	1	0.10%
Marshall	7	0.72%
Maury	13	1.33%
McMinn	4	0.41%
McNairy	3	0.31%
Meigs	2	0.21%
Monroe	7	0.72%
Montgomery	33	3.39%
Moore	1	0.10%
Morgan	4	0.41%
Obion		0.00%
Overton	3	0.31%
Perry	1	0.10%
Pickett	0	0.00%
Polk	3	0.31%
Putnam	13	1.33%
Rhea	2	0.21%
Roane	10	1.03%

Robertson	25	2.57%
Rutherford	52	5.34%
Scott	4	0.41%
Sequatchie	1	0.10%
Sevier	26	2.67%
Shelby	73	7.49%
Smith	1	0.10%
Stewart	5	0.51%
Sullivan	30	3.08%
Sumner	62	6.37%
Tipton	5	0.51%
Trousdale	1	0.10%
Unicoi	6	0.62%
Union	4	0.41%
Van Buren	2	0.21%
Warren	4	0.41%
Washington	32	3.29%
Wayne	1	0.21%
Weakley	2	0.21%
White	5	0.51%
Williamson	28	2.87%
Wilson	19	1.95%
Total	975	100.00%

2017 – Pharmacy – Historical Utilization By Syringe Count

Section B, Need, Item F

Service Area Counties	Historical Utilization - County Residents	% of Total Procedures
Anderson	38	0.88%
Bedford	41	0.95%
Benton	18	0.42%
Bledsoe	0	0.00%
Blount	56	1.30%
Bradley	21	0.49%
Campbell	10	0.23%
Cannon	13	0.30%
Carroll	7	0.16%
Carter	13	0.30%
Cheatham	44	1.02%
Chester	11	0.25%
Claiborne	15	0.35%
Clay	7	0.16%
Cocke	44	1.02%
Coffee	92	2.13%
Crockett	15	0.35%
Cumberland	40	0.93%
Davidson	285	6.60%
Decatur	24	0.56%
DeKalb	44	1.02%
Dickson	19	0.44%
Dyer	24	0.56%
Fayette	41	0.95%
Fentress	0	0.00%
Franklin	67	1.55%
Gibson	51	1.18%
Giles	22	0.51%
Grainger	30	0.69%
Greene[3]	47	1.09%
Grundy	5	0.12%

[3] County includes one patient from Limestone Community

Hamblen[4]	109	2.52%
Hamilton	91	2.11%
Hancock	6	0.14%
Hardeman	26	0.60%
Hardin	5	0.12%
Hawkins	19	0.44%
Haywood	8	0.19%
Henderson	20	0.46%
Henry	2	0.05%
Hickman	22	0.51%
Houston	8	0.19%
Humphreys	6	0.14%
Jackson	0	0.00%
Jefferson	71	1.64%
Johnson	13	0.30%
Knox	258	5.97%
Lake	9	0.21%
Lauderdale	33	0.76%
Lawrence	41	0.95%
Lewis	7	0.16%
Lincoln	67	1.55%
Loudon	35	0.81%
Macon	36	0.83%
Madison	101	2.34%
Marion	2	0.05%
Marshall	11	0.25%
Maury	38	0.88%
McMinn	13	0.30%
McNairy	18	0.42%
Meigs	5	0.12%
Monroe	39	0.90%
Montgomery	182	4.21%
Moore	5	0.12%
Morgan	12	0.28%
Obion	23	0.53%
Overton	16	0.37%
Perry	4	0.09%
Pickett	0	0.00%
Polk	7	0.16%
Putnam	72	1.67%

[4] County includes patient(s) from Umatilla Community

Supplemental #2
June 15, 2018
11:27 A.M.

Nursing – 2019 Projected Utilization By Patient Count

Based on 2017 Pharmacy Utilization Data

Section B, Need, Item F

Service Area Counties	Projected Utilization	% of Total Procedures
Anderson	1	0.99%
Bedford	1	0.99%
Benton		
Bledsoe		
Blount	1	0.99%
Bradley	1	0.99%
Campbell	1	0.99%
Cannon	0	
Carroll		
Carter	1	0.99%
Cheatham	1	0.99%
Chester		
Claiborne		
Clay		
Cocke	1	0.99%
Coffee	1	0.99%
Crockett		
Cumberland		
Davidson	12	11.88%
Decatur		
DeKalb	1	0.99%
Dickson	1	0.99%
Dyer		
Fayette	1	0.99%
Fentress		
Franklin		
Gibson		
Giles		
Grainger	1	0.99%
Greene	1	0.99%
Grundy		
Hamblen	3	2.97%
Hamilton		

Hancock		
Hardeman	1	0.99%
Hardin		
Hawkins	1	0.99%
Haywood	1	0.99%
Henderson		
Henry		
Hickman	1	0.99%
Houston		
Humphreys		
Jackson		
Jefferson	2	1.98%
Johnson	1	0.99%
Knox	6	5.94%
Lake		
Lauderdale	1	0.99%
Lawrence		
Lewis	1	0.99%
Lincoln		
Loudon		
Macon	1	0.99%
Madison	2	1.98%
Marion	1	0.99%
Marshall	1	0.99%
Maury	1	0.99%
McMinn	1	0.99%
McNairy	1	0.99%
Meigs	1	0.99%
Monroe		
Montgomery	3	2.97%
Moore		
Morgan		
Obion		
Overton		
Perry		
Pickett		
Polk		0.00%
Putnam		
Rhea		
Roane		0.00%
Robertson	3	2.97%

Rutherford	5	4.95%
Scott		
Sequatchie		
Sevier		
Shelby	7	6.93%
Smith		
Stewart		
Sullivan	3	2.97%
Sumner	6	5.94%
Tipton		
Trousdale		
Unicoi		
Union		
Van Buren		
Warren	1	0.99%
Washington	13	12.87%
Wayne		
Weakley		
White		
Williamson	3	2.97%
Wilson	4	3.96%
Total	101	100.00%

Projected utilization of nursing services is based on 2017 pharmaceutical services usage. ANS anticipates serving 103 patients in 2019 with an average utilization of approximately three visits per patient. While the average patient receives 5.5 refills per year, our projected utilization takes into consideration rolling/staggered enrollment of patients onto our home care services program in Year 1.

Supplemental #2
June 15, 2018
11:27 A.M.

Service Area Counties	Visits	% of Total Procedu	Visits	% of Total Procedures
Anderson	3	0.99%	5	0.81%
Bedford	3	0.99%	5	0.81%
Benton				
Bledsoe				
Blount	3	0.99%	5	0.81%
Bradley	3	0.99%	5	0.81%
Campbell	3	0.99%	5	0.81%
Cannon			5	0.81%
Carroll				
Carter	3	0.99%	5	0.81%
Cheatham	3	0.99%	5	0.81%
Chester				
Claiborne				
Clay				
Cocke	3	0.99%	5	0.81%
Coffee	3	0.99%	5	0.81%
Crockett				
Cumberland				
Davidson	38	12.50%	83	13.47%
Decatur				
DeKalb	3	0.99%	5	0.81%
Dickson	3	0.99%	10	1.62%
Dyer				
Fayette	3	0.99%	5	0.81%
Fentress				
Franklin				
Gibson				
Giles				
Grainger	3	0.99%	5	0.81%
Greene	3	0.99%	5	0.81%
Grundy				
Hamblen	6	1.97%	15	2.44%
Hamilton				
Hancock				
Hardeman	3	0.99%	5	0.81%
Hardin				
Hawkins	3	0.99%	5	0.81%
Haywood	3	0.99%	5	0.81%
Henderson				
Henry				
Hickman	3	0.99%	5	0.81%
Houston				
Humphreys				
Jackson				
Jefferson	6	1.97%	10	1.62%

Service Area Counties	Visits	% of Total Procedu	Visits	% of Total Procedures
Johnson	3	0.99%	5	0.81%
Knox	18	5.92%	28	4.55%
Lake				
Lauderdale	3	0.99%	5	0.81%
Lawrence				
Lewis	3	0.99%	5	0.81%
Lincoln				
Loudon				
Macon	3	0.99%	5	0.81%
Madison	6	1.97%	10	1.62%
Marion	3	0.99%	5	0.81%
Marshall	3	0.99%	5	0.81%
Maury	3	0.99%	5	0.81%
McMinn	3	0.99%	5	0.81%
McNairy	3	0.99%	5	0.81%
Meigs	3	0.99%	5	0.81%
Monroe				
Montgomery	9	2.96%	15	2.44%
Moore				
Morgan				
Obion				
Overton				
Perry				
Pickett				
Polk		0.00%		
Putnam				
Rhea				
Roane		0.00%		
Robertson	9	2.96%	15	2.44%
Rutherford	15	4.93%	75	12.18%
Scott				
Sequatchie				
Sevier				
Shelby	21	6.91%	45	7.31%
Smith				
Stewart				
Sullivan	9	2.96%	15	2.44%
Sumner	18	5.92%	35	5.68%
Tipton				
Trousdale				
Unicoi				
Union				
Van Buren				
Warren	3	0.99%	5	0.81%
Washington	41	13.49%	73	11.85%
Wayne				

Service Area Counties	Visits	% of Total Procedu	Visits	% of Total Procedures
Weakley				
White				
Williamson	9	2.96%	22	3.57%
Wilson	12	3.95%	20	3.25%
Total	304	100.00%	616	100.00%

Nursing – 2020 Projected Utilization By Patient Count

Based on 2017 Pharmacy Utilization Data & Projected Growth

Section B, Need, Item F

Service Area Counties	Projected Utilization	% of Total Procedures
Anderson	1	0.89%
Bedford	1	0.89%
Benton		
Bledsoe		
Blount	1	0.89%
Bradley	1	0.89%
Campbell	1	0.89%
Cannon*	1	0.89%
Carroll		
Carter	1	0.89%
Cheatham	1	0.89%
Chester		
Claiborne		
Clay		
Cocke	1	0.89%
Coffee	1	0.89%
Crockett		
Cumberland		
Davidson*	15	13.39%
Decatur		
DeKalb	1	0.89%
Dickson*	2	1.79%
Dyer		
Fayette	1	0.89%
Fentress		
Franklin		
Gibson		
Giles		
Grainger	1	0.89%
Greene	1	0.99%
Grundy		
Hamblen	3	2.68%
Hamilton		

Supplemental #2
June 15, 2018
11:27 A.M.

Hancock		
Hardeman	1	0.89%
Hardin		
Hawkins	1	0.89%
Haywood	1	0.89%
Henderson		
Henry		
Hickman	1	0.89%
Houston		
Humphreys		
Jackson		
Jefferson	2	1.79%
Johnson	1	0.89%
Knox	6	5.36%
Lake		
Lauderdale	1	0.89%
Lawrence		
Lewis	1	0.89%
Lincoln		
Loudon		
Macon	1	0.89%
Madison	2	1.79%
Marion	1	0.89%
Marshall	1	0.89%
Maury	1	0.89%
McMinn	1	0.89%
McNairy	1	0.89%
Meigs	1	0.89%
Monroe		
Montgomery	3	2.68%
Moore		
Morgan		
Obion		
Overton		
Perry		
Pickett		
Polk		
Putnam		
Rhea		
Roane		
Robertson	3	2.68%

Rutherford	5	4.46%
Scott		
Sequatchie		
Sevier		
Shelby*	9	8.04%
Smith		
Stewart		
Sullivan	3	2.68%
Sumner*	7	6.25%
Tipton		
Trousdale		
Unicoi		
Union		
Van Buren		
Warren	1	0.89%
Washington	15	13.39%
Wayne		
Weakley		
White		
Williamson*	4	3.57%
Wilson	4	3.57%
Total	112	100.00%

Tennessee Pharmaceutical Utilization in 2017

Number of Syringes: 4,319

Cluster Map Showing Usage by County

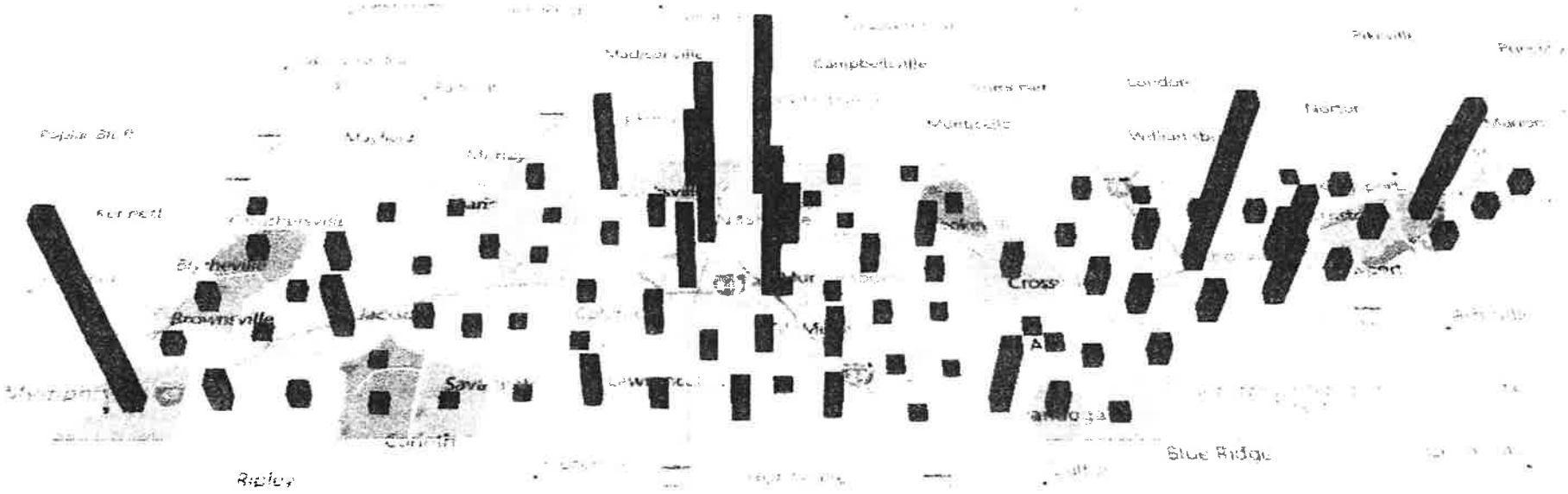
Collapsed Map Showing Coverage in Tennessee

Supplemental #2
June 15, 2018
11:27 A.M.

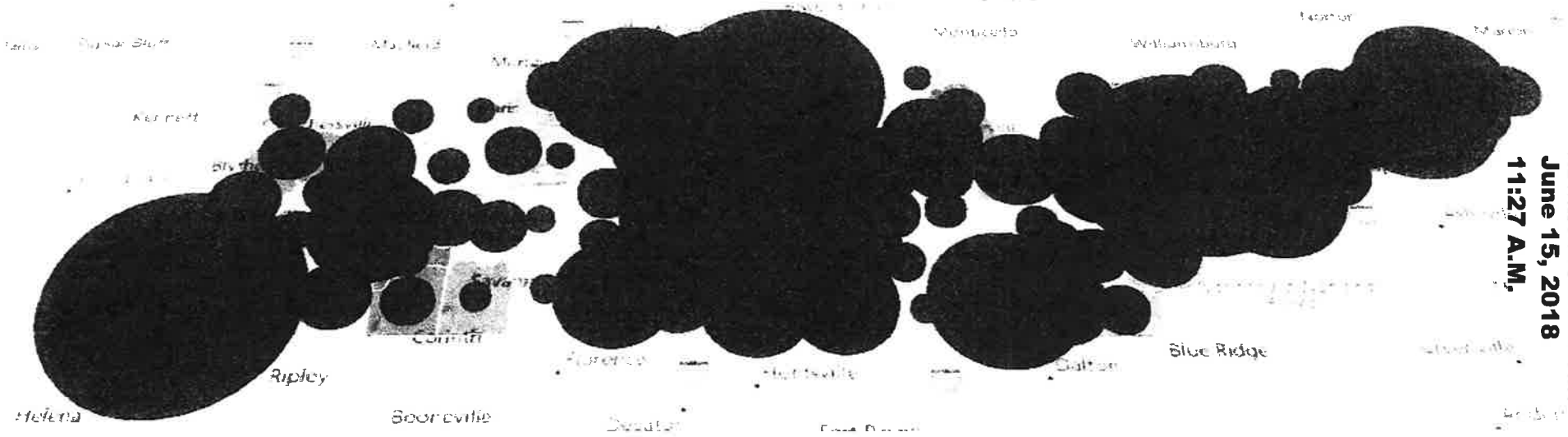
Tennessee Pharmaceutical Patients in 2017

Number of Patient: 975

Cluster Map Showing Patients by County



Collapsed Map Showing Coverage in Tennessee



Supplemental Response:

18. Section B. Economic Feasibility Item B Funding

Supplemental Attachment 19

Financial Statement

Bank Letter

Supplemental #2
June 15, 2018
11:27 A.M.

GUARANTY AGREEMENT
BETWEEN
BOND PHARMACY, INC. DBA ADVANCED INFUSION SOLUTIONS
AND
INTRATHECAL CARE SOLUTIONS, LLC DBA ADVANCED NURSING SOLUTIONS

1. Definitions. Capitalized terms used in this Agreement and not otherwise defined herein have the meanings set forth below:
   - **a.** "Project" shall be defined as the Certificate of Need application submitted to form a home health agency in Tennessee.
   - **b.** "Guarantor" shall be defined as Bond Pharmacy, Inc. dba Advanced Infusion Solutions.
   - **c.** "Guarantee" shall be defined as Intrathecal Care Solutions, LLC dba Advanced Nursing Solutions.
   - **d.** "Obligations" shall mean all monetary obligations necessary to fund Project, including obligations for legal, administrative and consultant fees, rent and fixed equipment costs.

2. Terms. Subject to the terms set forth herein, Guarantor unconditionally guarantees funding of Project as a secondary obligor. Guarantor further agrees that its guaranty hereunder constitutes a guaranty of payment when due and waives any right to require Guarantee to resort to any security or credit that Guarantee may have with a third party.

3. Entire agreement. Acceptance of this Agreement by constitutes the entire agreement between the Parties with respect to Project and will supersede all prior agreements or understandings between the Parties with respect to the Services.

IN WITNESS WHEREOF, the Guarantor hereto have duly executed this Agreement as of the day and year written below.

ADVANCED INFUSION SOLUTIONS

By: _____

Name: SIMON CASTELLANOS

Title: CEO

Date: 6/5/2018

Address: _____

623 Highland Colony Parkway, Ste. 100
Ridgeland, MS 39157

ADVANCED NURSING SOLUTIONS

By: _____

Name: SIMON CASTELLANOS

Title: CEO

Date: 6/5/2018

623 Highland Colony Parkway, Ste. 100
Ridgeland, MS 39157

Supplemental #2
June 15, 2018
11:27 A.M.

Advanced Infusion Solutions Holdings, LLC and Subsidiaries

Consolidated Financial Statements

Years Ended December 31, 2017 and 2016

DHG
DIXON HUGHES GOODMAN LLP

DHG
DIXON HUGHES GOODMAN LLP

Independent Auditors' Report

Board of Directors
Advanced Infusion Solutions Holdings, LLC and Subsidiaries
Ridgeland, Mississippi

We have audited the accompanying consolidated financial statements of Advanced Infusion Solutions Holdings, LLC and Subsidiaries (collectively, the "Company"), which comprise the consolidated balance sheets as of December 31, 2017 and 2016 and the related consolidated statements of operations, changes in members' deficit, and cash flows for the years then ended, and the related notes to the consolidated financial statements.

Management's Responsibility for the Consolidated Financial Statements
Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of the consolidated financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility
Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Company's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion
In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Advanced Infusion Solutions Holdings, LLC and Subsidiaries as of December 31, 2017 and 2016, and the results of their operations and their cash flows for the years then ended, in accordance with accounting principles generally accepted in the United States of America.

Dixon Hughes Goodman LLP

Birmingham, Alabama
April 23, 2018

Advanced Infusion Solutions
Consolidated Balance Sheet
Condensed version of audited balance sheet

	2017	2016
Total Current Assets	$26,534	$16,297
Net Fixed Assets	$7,939	$5,728
Total Other Assets	$123,863	$82,323
TOTAL ASSETS	$158,336	$104,348
Total Current Liabilities	$22,610	$7,507
Total LT Liabilities	$213,192	$107,289
Total Liabilities	$235,802	$114,797
Total Stockholder's Equity	($77,466)	($10,448)
TOTAL LIABILITIES & EQUITY	$158,336	$104,348

Advanced Infusion Solutions
Consolidated Income Statement
Condensed version of audited income statement

	2017	2016
Net Revenue	$84,274,185	$56,664,958
Operating Expenses	($69,526,676)	($32,037,915)
Operating Income	$14,747,509	$24,627,043
Non-Operating Expenses	($12,924,458)	($13,385,446)
Net Income	$1,823,051	$11,241,597

Advanced Infusion Solutions
Consolidated Balance Sheet
unaudited

	Apr-18
Total Current Assets	$30,971
Net Fixed Assets	$10,025
Total Other Assets	$122,031
TOTAL ASSETS	$163,027
Total Current Liabilities	$21,333
Total LT Debt	$212,147
Total Liabilities	$239,774
Total Stockholder's Equity	($76,748)
TOTAL LIABILITIES & EQUITY	$163,027

Advanced Infusion Solutions
Consolidated Income Statement
April 2018 YTD
unaudited

	2018
Net Revenue	$37,853,042
Operating Expenses	($28,358,165)
Operating Income	$9,494,877
Non-Operating Expenses	($8,775,955)
Net Income	$718,922

BOND PHARMACY, INC.
D/B/A ADVANCED INFUSION SOLUTIONS
OPERATING ACCOUNT
623 HIGHLAND COLONY PKWY
SUITE 100
RIDGELAND MS 39157

ACCOUNT SUMMARY FOR PERIOD DECEMBER 01, 2017 - DECEMBER 29, 2017

Commercial Analyzed Ckg [redacted] **BOND PHARMACY, INC.**

Previous Balance 11/30/17	$3,835,010.13	Number of Days in Cycle	29
41 Deposits/Credits	$5,580,163.29	Minimum Balance This Cycle	$1,405,791.45
486 Checks/Debits	($8,009,381.97)	Average Collected Balance	$3,905,065.13
Service Charges	$0.00		
Ending Balance 12/29/17	$1,405,791.45		

ACCOUNT DETAIL FOR PERIOD DECEMBER 01, 2017 - DECEMBER 29, 2017

Commercial Analyzed Ckg [redacted] **BOND PHARMACY, INC.**

Date	*Description*	*Deposits/Credits*	*Withdrawals/Debits*	*Resulting Balance*
12/01	Target balance account credit FROM CHECKING ACCT 7527711503	$219,170.64		$4,054,180.77
12/01	Target balance account credit FROM CHECKING ACCT 7527711481	$8,823.36		$4,063,004.13
12/01	Wire transfer withdrawal BRADLEY PHILLIPS 120117 USD0002594373		$20,000.00	$4,043,004.13
12/01	ACH Withdrawal GREAT-WEST LIFE PAYMENTS 120117 0005Bond Pharmacy, I 170014372668		$24,572.05	$4,018,432.08
12/01	ACH Withdrawal U. P. S. UPS BILL 120117 ADVANCED INFUSION SOLU 173290000A4914R		$16,860.12	$4,001,571.96
12/01	ACH Withdrawal GREAT-WEST LIFE PAYMENTS 120117 0005Bond Pharmacy, I 170014372667		$11,749.17	$3,989,822.79
12/01	ACH Withdrawal PAY PLUS ACHTRANS 120117 ZP Account 5 452579291		$0.72	$3,989,822.07
12/01	Check 8864		$11,761.34	$3,978,060.73
12/01	Check 8841		$4,693.50	$3,973,367.23

Thank you for banking with us.

Supplemental #2

Capital One Bank
Commercial Banking Group

MANAGE YOUR CASH

CASH MANAGEMENT CHECKING MONEY MARKET CDs LOANS

June 15, 2018
11:27 A.M.

BOND PHARMACY, INC.
D/B/A ADVANCED INFUSION SOLUTIONS
OPERATING ACCOUNT
623 HIGHLAND COLONY PKWY
SUITE 100
RIDGELAND MS 39157

▸ Contact your Relationship Manager to discuss targeted solutions for your evolving business needs.

ACCOUNT SUMMARY FOR PERIOD APRIL 01, 2018 - APRIL 30, 2018

Commercial Analyzed Ckg [redacted] **BOND PHARMACY, INC.**

Previous Balance 03/31/18	$4,515,834.72	Number of Days in Cycle	30
42 Deposits/Credits	$5,990,519.04	Minimum Balance This Cycle	$1,887,881.83
322 Checks/Debits	($8,618,471.93)	Average Collected Balance	$3,501,734.51
Service Charges	$0.00		
Ending Balance 04/30/18	$1,887,881.83		

ACCOUNT DETAIL FOR PERIOD APRIL 01, 2018 - APRIL 30, 2018

Commercial Analyzed Ckg [redacted] **BOND PHARMACY, INC.**

Date	Description	Deposits/Credits	Withdrawals/Debits	Resulting Balance
04/02	Target balance account credit FROM CHECKING ACCT 7527711503	$145,150.41		$4,660,985.13
04/02	Target balance account credit FROM CHECKING ACCT 7527711481	$3,042.51		$4,664,027.64
04/02	ACH Withdrawal AMERISOURCE BERG PAYMENTS 040218 ADVANCED INFUSION SOLU 0100004107		$6,978.95	$4,657,048.69
04/02	ACH Withdrawal POSTALIA TDCPOSTAGE 040218 BOND PHARMACY 106000538160		$1,000.00	$4,656,048.69
04/02	Check 9896		$5,881.73	$4,650,166.96
04/02	Check 9886		$975.00	$4,649,191.96
04/02	Check 9946		$147.17	$4,649,044.79
04/03	Target balance account credit FROM CHECKING ACCT 7527711503	$835,412.90		$5,484,457.69
04/03	Target balance account credit FROM CHECKING ACCT 7527711481	$4,925.09		$5,489,382.78
04/03	Wire transfer withdrawal BRADLEY PHILLIPS 040318 USD0003130844		$20,000.00	$5,469,382.78

Thank you for banking with us.

Supplemental #2
June 15, 2018
11:27 A.M.

Supplemental Response:

19. Section B. Economic Feasibility Item D Projected Data Chart

Supplemental Attachment 20- (R-29), (R-30)

Projected Data Chart, Nursing

Supplemental Attachment 21

Projected Data Charts for Nursing, Pharmaceuticals & Nursing Pharmaceuticals

REVISED: PROJECTED DATA CHART - NURSING

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

		Year 2019	Year 2020
A.	Utilization Data (Specify unit of measure, e.g., 1,000 patient days, 500 visits)	Visits 304	Visits 616
B.	Revenue from Services to Patients		
	1. Inpatient Services	$	$
	2. Outpatient Services		
	3. Emergency Services		
	4. Other Operating Revenue (Specify) Home Nursing Services	$ 86,887	$ 176,061
	Gross Operating Revenue	**$ 86,887**	**$ 176,061**
C	Deductions from Gross Operating Revenue		
	1. Contractual Adjustments	$ 54,173	$ 109,771
	2. Provision for Charity Care	869	1,761
	3. Provisions for Bad Debt	2,607	5,282
	Total Deductions	$ 57,649	$ 116,814
NET OPERATING REVENUE		$ 29,238	$ 59,247
D.	Operating Expenses		
	1. Salaries and Wages		
	a. Direct Patient Care	154,551	214,654
	b. Non-Patient Care	11,520	16,000
	2. Physician's Salaries and Wages		
	3. Supplies	3,648	7,392
	4. Rent		
	a. Paid to Affiliates		
	b. Paid to Non-Affiliates	9,000	9,000
	5. Management Fees:		
	a. Paid to Affiliates		
	b. Paid to Non-Affiliates		
	6. Other Operating Expenses	11,400	13,500
	Total Operating Expenses	$ 190,119	$ 260,546
E.	**Earnings Before Interest, Taxes and Depreciation**	$ (160,880)	$ (201,299)
F.	Non-Operating Expenses		
	1. Taxes	$ (35,687)	$ (44,579)
	2. Depreciation	1,333	1,333
	3. Interest		
	4. Other Non-Operating Expenses		
	Total Non-Operating Expenses	$ (34,354)	$ (43,246)
NET INCOME (LOSS)		$ (126,526)	$ (158,053)

Chart Continues Onto Next Page

Supplemental #2
June 15, 2018
11:27 A.M.

NET INCOME (LOSS)	$ (126,526)	$ (158,053)
G. Other Deductions		
1. Estimated Annual Principal Debt Repayment	$ -0-	$ -0-
2. Annual Capital Expenditure	4,000	-0-
Total Other Deductions	$ 4,000	$ -0-
NET BALANCE	$ (122,526)	$ (158,053)
DEPRECIATION	$ 1,333	$ 1,333
FREE CASH FLOW (Net Balance + Depreciation)	$ (121,193)	$ (156,720)

PROJECTED DATA CHART - Nursing

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

		Year 2019	Year 2020
A.	Utilization Data (Specify unit of measure, e.g., 1,000 patient days, 500 visits)	Visits 304	Visits 616
B.	Revenue from Services to Patients		
	1. Inpatient Services	$	$
	2. Outpatient Services		
	3. Emergency Services		
	4. Other Operating Revenue (Specify) Home Nursing Services	$ 86, 887	$ 176,061
	Gross Operating Revenue	**$ 86,887**	**$ 176,061**
C	Deductions from Gross Operating Revenue		
	1. Contractual Adjustments	$ 54,173	$ 109,771
	2. Provision for Charity Care	869	1,761
	3. Provisions for Bad Debt	2,607	5,282
	Total Deductions	$ 57,649	$ 116,814
NET OPERATING REVENUE		$ 29,238	$ 59,247
D.	Operating Expenses		
	1. Salaries and Wages		
	a. Direct Patient Care	154,551	214,654
	b. Non-Patient Care	11,520	16,000
	2. Physician's Salaries and Wages		
	3. Supplies	3,648	7,392
	4. Rent		
	a. Paid to Affiliates		
	b. Paid to Non-Affiliates	9,000	9,000
	5. Management Fees:		
	a. Paid to Affiliates		
	b. Paid to Non-Affiliates		
	6. Other Operating Expenses	11,400	13,500
	Total Operating Expenses	$ 190,119	$ 260,546
E.	**Earnings Before Interest, Taxes and Depreciation**	$ (160,880)	$ (201,299)
F.	Non-Operating Expenses		
	1. Taxes	$ (35,687)	$ (44,579)
	2. Depreciation	1,333	1,333
	3. Interest		
	4. Other Non-Operating Expenses		
	Total Non-Operating Expenses	$ (34,354)	$ (43,246)
NET INCOME (LOSS)		$ (126,526)	$ (158,053)

Chart Continues Onto Next Page

Supplemental #2
June 15, 2018
11:27 A.M.

NET INCOME (LOSS)	$ (126,526)	$ (158,053)
G. Other Deductions		
1. Estimated Annual Principal Debt Repayment	$ -0-	$ -0-
2. Annual Capital Expenditure	4,000	-0-
Total Other Deductions	$ 4,000	$ -0-
NET BALANCE	$ (122,526)	$ (158,053)
DEPRECIATION	$ 1,333	$ 1,333
FREE CASH FLOW (Net Balance + Depreciation)	$ (121,193)	$ (156,720)

REVISED: PROJECTED DATA CHART - PHARMACY

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

		Year 2019	Year 2020
A.	Utilization Data (Specify unit of measure, e.g., 1,000 patient days, 500 visits)	Visits 304	Visits 616
B.	Revenue from Services to Patients		
	1. Inpatient Services	$	$
	2. Outpatient Services		
	3. Emergency Services		
	4. Other Operating Revenue (Specify) Home Nursing Services Pharmaceuticals	$ 409,617	830,013
	Gross Operating Revenue	**$ 409,617**	**$ 830,013**
C	Deductions from Gross Operating Revenue		
	1. Contractual Adjustments	$ 180,231	$ 365,206
	2. Provision for Charity Care	4,096	8,300
	3. Provisions for Bad Debt	12,289	24,900
	Total Deductions	$ 196,616	$ 398,406
NET OPERATING REVENUE		$ 213,001	$ 431,607
D.	Operating Expenses		
	1. Salaries and Wages		
	a. Direct Patient Care	19,275	39,058
	b. Non-Patient Care		
	2. Physician's Salaries and Wages		
	3. Supplies	17,085	34,619
	4. Rent		
	a. Paid to Affiliates		
	b. Paid to Non-Affiliates		
	5. Management Fees:		
	a. Paid to Affiliates		
	b. Paid to Non-Affiliates		
	6. Other Operating Expenses	42,936	87,003
	Total Operating Expenses	$ 79,297	$ 160,680
E.	**Earnings Before Interest, Taxes and Depreciation**	$ 133,704	$ 270,927
F.	Non-Operating Expenses		
	1. Taxes	$ 29,415	$ 59,604
	2. Depreciation		
	3. Interest		
	4. Other Non-Operating Expenses		
	Total Non-Operating Expenses	$ 29,415	$ 59,604
NET INCOME (LOSS)		$ 104,289	$ 211,323

Chart Continues Onto Next Page

Supplemental #2
June 15, 2018
11:27 A.M.

NET INCOME (LOSS)	$ 104,289	$ 211,323
G. Other Deductions		
1. Estimated Annual Principal Debt Repayment	$ -0-	$ -0-
2. Annual Capital Expenditure	-0-	-0-
Total Other Deductions	$ -0-	$ -0-
NET BALANCE	$ 104,289	$ 211,323
DEPRECIATION	$ -0-	$ -0-
FREE CASH FLOW (Net Balance + Depreciation)	$ 104,289	$ 211,323

REVISED: PROJECTED DATA CHART - CONSOLIDATED

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

		Year 2019	Year 2020
A.	Utilization Data (Specify unit of measure, e.g., 1,000 patient days, 500 visits)	Visits 304	Visits 616
B.	Revenue from Services to Patients		
	1. Inpatient Services	$	$
	2. Outpatient Services		
	3. Emergency Services		
	4. Other Operating Revenue (Specify) Home Nursing Services Pharmaceuticals	$ 496,504	1,006,074
	Gross Operating Revenue	$ 496,504	$ 1,006,074
C	Deductions from Gross Operating Revenue		
	1. Contractual Adjustments	$ 234,404	$ 474,977
	2. Provision for Charity Care	4,965	10,061
	3. Provisions for Bad Debt	14,895	30,182
	Total Deductions	$ 254,264	$ 515,220
NET OPERATING REVENUE		$ 242,239	$ 490,854
D.	Operating Expenses		
	1. Salaries and Wages		
	a. Direct Patient Care	173,826	253,712
	b. Non-Patient Care	11,520	16,000
	2. Physician's Salaries and Wages		
	3. Supplies	20,733	42,011
	4. Rent		
	a. Paid to Affiliates		
	b. Paid to Non-Affiliates	9,000	9,000
	5. Management Fees:		
	a. Paid to Affiliates		
	b. Paid to Non-Affiliates		
	6. Other Operating Expenses	54,336	100,503
	Total Operating Expenses	$ 269,415	$ 421,226
E.	**Earnings Before Interest, Taxes and Depreciation**	$ (27,176)	$ 69,628
F.	Non-Operating Expenses		
	1. Taxes	$ (6,272)	$ 15,025
	2. Depreciation	1,333	1,333
	3. Interest		
	4. Other Non-Operating Expenses		
	Total Non-Operating Expenses	$ (4,939)	$ 16,358
NET INCOME (LOSS)		$ (22,237)	$ 53,270

Chart Continues Onto Next Page

Supplemental #2
June 15, 2018
11:27 A.M.

NET INCOME (LOSS)	$ (22,237)	$ 53,270
G. Other Deductions		
1. Estimated Annual Principal Debt Repayment	$ -0-	$ -0-
2. Annual Capital Expenditure	4,000	-0-
Total Other Deductions	$ 4,000	$ -0-
NET BALANCE	$ (18,237)	$ 53,270
DEPRECIATION	$ 1,333	$ 1,333
FREE CASH FLOW (Net Balance + Depreciation)	$ (16,904)	$ 54,603

Supplemental Response:

20. Section B, Economic Feasibility, Item E.1

Supplemental Attachment 22- (R-31)

Revised Page 31

Section B, Economic Feasibility, Item E.1
Revised Page 31

Nursing Only	Year One	Year Two	% Change (Current Year to Year 2)
Gross Charge *(Gross Revenue/Patient Revenue/Visit*	1,573 286	1,573 286	0%
Deduction from Revenue *Deduction/Patient Deductions/Visit*	1,043 190	1,043 190	0%
Average Net Charge *(Net Operating Revenue/Patient Revenue/Visit*	529 96	529 96	0%

Pharmaceuticals Only	Year One	Year Two	% Change (Current Year to Year 2)
Gross Charge *(Gross Revenue/Patient Revenue/Visit*	7,414 1,347	7,414 1,347	0%
Deduction from Revenue *Deduction/Patient Deductions/Visit*	3,559 647	3,559 647	0%
Average Net Charge *(Net Operating Revenue/Patient Revenue/Visit*	3,855 701	3,855 701	0%

Nursing and Pharmaceuticals	Year One	Year Two	% Change (Current Year to Year 2)
Gross Charge *(Gross Revenue/Patient Revenue/Visit*	8,986 1,633	8,983 1,633	0%
Deduction from Revenue *Deduction/Patient Deductions/Visit*	4,602 836	4,602 836	0%
Average Net Charge *(Net Operating Revenue/Patient Revenue/Visit*	4,384 797	4,384 797	0%

Supplemental #2
June 15, 2018
11:27 A.M.

Supplemental Response:

21. Section B, Economic Feasibility, Item E.3

Supplemental Attachment 23

Fee Comparison - JAR Data

	Medicare Certified Home Care Organization								Private Duty Company			
	Charge Per Visit - Direct Only		Charge Per Visit - Direct & Indirect		Charge Per Episode of Care - Direct Only		Charge Per Episode of Care - Direct & Indirect		Average Charge Per Visit		Average Charge Per Hour	
	Infusion Therapy - Pain Management	Infusion Therapy - Other	Infusion Therapy - Pain Management	Infusion Therapy - Other	Infusion Therapy - Pain Management	Infusion Therapy - Other	Infusion Therapy - Pain Management	Infusion Therapy - Other	Infusion Therapy - Pain Management	Infusion Therapy - Other	Infusion Therapy - Pain Management	Infusion Therapy - Other
Cumberland River Homecare (14024)	0	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Suncrest Home Health (19324)	145	0	145	0	145	0	145	0	150	0	75	0
Suncrest Home Health (13032)	138	138	138	138	138	138	138	138	n/a	n/a	75	75
Suncrest Homes Health (21024)	0	0	0	0	0	0	0	0	0	0	0	0
Home Care Solutions (19544)	0	0	0	0	0	0	0	0	n/a	n/a	n/a	n/a
Coram CVS Specialty Infusion Services (19734)	1	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Vanderbilt Affiliated Walgreens Services (19994)		120										
Procare Home Health Services (30051)	175	175	175	175	175	175	175	175	0	0	0	0
Maxim Healthcare Services (33433)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	120	n/a	30
Henry County Medical Center Home Health (40075)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
NHC Homecare (60024)	0	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Still Waters Home Health Agency (79526)	110	110	110	110	110	110	110	110	n/a	n/a	n/a	n/a
Coram CVS/Specialty Infusion Service (79556)	1	1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

	Charge Per Visit - Direct Only	Charge Per Visit - Direct & Indirect	Charge Per Episode of Care - Direct Only	Charge Per Episode of Care - Direct & Indirect	Average Charge Per Visit	Average Charge Per Hour
*Pentec Health	275	275				

*It is our assumption that the charge per visit for skilled nursing applies to Pentec's intrathecal infusion business.

	Proposed Charges
Implanted Pump Management, LLC	200
* Proposed in Certificate of Need	

Supplemental Response:

22. Section B, Economic Feasibility, Item F. 1

Supplemental Attachment 24

Supplemental #2
June 15, 2018
11:27 A.M.

GUARANTY AGREEMENT
BETWEEN
BOND PHARMACY, INC. DBA ADVANCED INFUSION SOLUTIONS
AND
INTRATHECAL CARE SOLUTIONS, LLC DBA ADVANCED NURSING SOLUTIONS

1. Definitions. Capitalized terms used in this Agreement and not otherwise defined herein have the meanings set forth below:
   - **a.** "Project" shall be defined as the Certificate of Need application submitted to form a home health agency in Tennessee.
   - **b.** "Guarantor" shall be defined as Bond Pharmacy, Inc. dba Advanced Infusion Solutions.
   - **c.** "Guarantee" shall be defined as Intrathecal Care Solutions, LLC dba Advanced Nursing Solutions.
   - **d.** "Obligations" shall mean all monetary obligations necessary to fund Project, including obligations for legal, administrative and consultant fees, rent and fixed equipment costs.

2. Terms. Subject to the terms set forth herein, Guarantor unconditionally guarantees funding of Project as a secondary obligor. Guarantor further agrees that its guaranty hereunder constitutes a guaranty of payment when due and waives any right to require Guarantee to resort to any security or credit that Guarantee may have with a third party.

3. Entire agreement. Acceptance of this Agreement by constitutes the entire agreement between the Parties with respect to Project and will supersede all prior agreements or understandings between the Parties with respect to the Services.

IN WITNESS WHEREOF, the Guarantor hereto have duly executed this Agreement as of the day and year written below.

ADVANCED INFUSION SOLUTIONS

By: _____

Name: Simon Cavendish

Title: CEO

Date: 6/5/2018

Address: _____

623 Highland Colony Parkway, Ste. 100
Ridgeland, MS 39157

ADVANCED NURSING SOLUTIONS

By: _____

Name: Simon Cavendish

Title: CEO

Date: 6/5/2018

623 Highland Colony Parkway, Ste. 100
Ridgeland, MS 39157

Supplemental #2
June 15, 2018
11:27 A.M.

Advanced Infusion Solutions Holdings, LLC and Subsidiaries

Consolidated Financial Statements

Years Ended December 31, 2017 and 2016

DHG
DIXON HUGHES GOODMAN LLP

DHG
DIXON HUGHES GOODMAN LLP

Independent Auditors' Report

Board of Directors
Advanced Infusion Solutions Holdings, LLC and Subsidiaries
Ridgeland, Mississippi

We have audited the accompanying consolidated financial statements of Advanced Infusion Solutions Holdings, LLC and Subsidiaries (collectively, the "Company"), which comprise the consolidated balance sheets as of December 31, 2017 and 2016 and the related consolidated statements of operations, changes in members' deficit, and cash flows for the years then ended, and the related notes to the consolidated financial statements.

Management's Responsibility for the Consolidated Financial Statements
Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of the consolidated financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility
Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Company's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion
In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Advanced Infusion Solutions Holdings, LLC and Subsidiaries as of December 31, 2017 and 2016, and the results of their operations and their cash flows for the years then ended, in accordance with accounting principles generally accepted in the United States of America.

Dixon Hughes Goodman LLP

Birmingham, Alabama
April 23, 2018

Advanced Infusion Solutions
Consolidated Balance Sheet
Condensed version of audited balance sheet

	2017	2016
Total Current Assets	$26,534	$16,297
Net Fixed Assets	$7,939	$5,728
Total Other Assets	$123,863	$82,323
TOTAL ASSETS	$158,336	$104,348
Total Current Liabilities	$22,610	$7,507
Total LT Liabilities	$213,192	$107,289
Total Liabilities	$235,802	$114,797
Total Stockholder's Equity	($77,466)	($10,448)
TOTAL LIABILITIES & EQUITY	$158,336	$104,348

Advanced Infusion Solutions
Consolidated Income Statement
Condensed version of audited income statement

	2017	2016
Net Revenue	$84,274,185	$56,664,958
Operating Expenses	($69,526,676)	($32,037,915)
Operating Income	$14,747,509	$24,627,043
Non-Operating Expenses	($12,924,458)	($13,385,446)
Net Income	$1,823,051	$11,241,597

Advanced Infusion Solutions
Consolidated Balance Sheet
unaudited

	Apr-18
Total Current Assets	$30,971
Net Fixed Assets	$10,025
Total Other Assets	$122,031
TOTAL ASSETS	$163,027
Total Current Liabilities	$21,333
Total LT Debt	$212,147
Total Liabilities	$239,774
Total Stockholder's Equity	($76,748)
TOTAL LIABILITIES & EQUITY	$163,027

Advanced Infusion Solutions
Consolidated Income Statement
April 2018 YTD
unaudited

	2018
Net Revenue	$37,853,042
Operating Expenses	($28,358,165)
Operating Income	$9,494,877
Non-Operating Expenses	($8,775,955)
Net Income	$718,922

BOND PHARMACY, INC.
D/B/A ADVANCED INFUSION SOLUTIONS
OPERATING ACCOUNT
623 HIGHLAND COLONY PKWY
SUITE 100
RIDGELAND MS 39157

▸ Contact your Relationship Manager to discuss targeted solutions for your evolving business needs.

ACCOUNT SUMMARY FOR PERIOD DECEMBER 01, 2017 - DECEMBER 29, 2017

Commercial Analyzed Ckg [redacted] **BOND PHARMACY, INC.**

Previous Balance 11/30/17	$3,835,010.13	Number of Days in Cycle	29
41 Deposits/Credits	$5,580,163.29	Minimum Balance This Cycle	$1,405,791.45
486 Checks/Debits	($8,009,381.97)	Average Collected Balance	$3,905,065.13
Service Charges	$0.00		
Ending Balance 12/29/17	$1,405,791.45		

ACCOUNT DETAIL FOR PERIOD DECEMBER 01, 2017 - DECEMBER 29, 2017

Commercial Analyzed Ckg [redacted] **BOND PHARMACY, INC.**

Date	Description	Deposits/Credits	Withdrawals/Debits	Resulting Balance
12/01	Target balance account credit FROM CHECKING ACCT 7527711503	$219,170.64		$4,054,180.77
12/01	Target balance account credit FROM CHECKING ACCT 7527711481	$8,823.36		$4,063,004.13
12/01	Wire transfer withdrawal BRADLEY PHILLIPS 120117 USD0002594373		$20,000.00	$4,043,004.13
12/01	ACH Withdrawal GREAT-WEST LIFE PAYMENTS 120117 0005Bond Pharmacy, I 170014372668		$24,572.05	$4,018,432.08
12/01	ACH Withdrawal U. P. S. UPS BILL 120117 ADVANCED INFUSION SOLU 173290000A4914R		$16,860.12	$4,001,571.96
12/01	ACH Withdrawal GREAT-WEST LIFE PAYMENTS 120117 0005Bond Pharmacy, I 170014372667		$11,749.17	$3,989,822.79
12/01	ACH Withdrawal PAY PLUS ACHTRANS 120117 ZP Account 5 452579291		$0.72	$3,989,822.07
12/01	Check 8864		$11,761.34	$3,978,060.73
12/01	Check 8841		$4,693.50	$3,973,367.23

Thank you for banking with us.

BOND PHARMACY, INC.
D/B/A ADVANCED INFUSION SOLUTIONS
OPERATING ACCOUNT
623 HIGHLAND COLONY PKWY
SUITE 100
RIDGELAND MS 39157

▸ Contact your Relationship Manager to discuss targeted solutions for your evolving business needs.

ACCOUNT SUMMARY FOR PERIOD APRIL 01, 2018 - APRIL 30, 2018

Commercial Analyzed Ckg [redacted] **BOND PHARMACY, INC.**

Previous Balance 03/31/18	$4,515,834.72	Number of Days in Cycle	30
42 Deposits/Credits	$5,990,519.04	Minimum Balance This Cycle	$1,887,881.83
322 Checks/Debits	($8,618,471.93)	Average Collected Balance	$3,501,734.51
Service Charges	$0.00		
Ending Balance 04/30/18	$1,887,881.83		

ACCOUNT DETAIL FOR PERIOD APRIL 01, 2018 - APRIL 30, 2018

Commercial Analyzed Ckg [redacted] **BOND PHARMACY, INC.**

Date	Description	Deposits/Credits	Withdrawals/Debits	Resulting Balance
04/02	Target balance account credit FROM CHECKING ACCT 7527711503	$145,150.41		$4,660,985.13
04/02	Target balance account credit FROM CHECKING ACCT 7527711481	$3,042.51		$4,664,027.64
04/02	ACH Withdrawal AMERISOURCE BERG PAYMENTS 040218 ADVANCED INFUSION SOLU 0100004107		$6,978.95	$4,657,048.69
04/02	ACH Withdrawal POSTALIA TDCPOSTAGE 040218 BOND PHARMACY 106000538160		$1,000.00	$4,656,048.69
04/02	Check 9896		$5,881.73	$4,650,166.96
04/02	Check 9886		$975.00	$4,649,191.96
04/02	Check 9946		$147.17	$4,649,044.79
04/03	Target balance account credit FROM CHECKING ACCT 7527711503	$835,412.90		$5,484,457.69
04/03	Target balance account credit FROM CHECKING ACCT 7527711481	$4,925.09		$5,489,382.78
04/03	Wire transfer withdrawal BRADLEY PHILLIPS 040318 USD0003130844		$20,000.00	$5,469,382.78

Thank you for banking with us.

Supplemental Response:

27. Section B, Orderly Development, Item

Supplemental Attachment 25

U.S. Food and Drug Administration (Bond Pharmacy Inc. dba Advanced Infusion Solutions)

Supplemental #2
June 15, 2018
11:27 A.M.

FDA: Closing of Inspection

Supplemental #2
June 15, 2018
11:27 A.M.

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

April 20, 2018

Simon Castellanos, CEO
Bond Pharmacy, Inc. dba Advanced Infusion Solutions
623 Highland Colony Pkwy, Suite 100
Ridgeland, Mississippi 39157-6077

Mr. Castellanos:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Bond Pharmacy, Inc. dba Advanced Infusion Solutions, located at 623 Highland Colony Pkwy, Suite 100, Ridgeland, Mississippi 39157- 6077, from November 6, 2017, to November 15, 2017, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Mississippi State Board of Pharmacy for follow up.

When the Agency concludes that an inspection is "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there is any question about the released information, please contact Mark Rivero at (504) 846-6103 or by email at Mark.Rivero@fda.hhs.gov.

Sincerely,

John W. Diehl -S Digitally signed by John W. Diehl -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl - S, 0.9.2342.19200300.100.1.1=2000099727
Date: 2018.04.20 23:30:22 -05'00'

LCDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations,
Division II

Enclosure: EIR, SHL

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division 2
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204
www.fda.gov

Supplemental #2
June 15, 2018
11:27 A.M.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	09/14/2015 - 10/27/2015
	FEI NUMBER 3011469631

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Charles R. Bell, Founder and President, COO

FIRM NAME	STREET ADDRESS
Advanced Infusion Solutions	132 Fairmont St Ste B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Clinton, MS 39056-4721	Producer of Sterile Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

- On 1/15/2015, air and surface samples collected and analyzed by Hayes Microbial Consulting found multiple organisms of bacteria and fungus in your ISO 5 and ISO 8 areas. Your firm did not provide sufficient evidence indicating these areas are free of microbial contamination prior to your firm beginning operations at this facility on 2/9/2015.

- Your firm's management states it performs surface and air monitoring in the ISO 5, ISO 7, and ISO 8 areas weekly. This is inadequate as environmental conditions are not performed each day sterile drug products are produced. In addition, the documentation provided by your firm indicates Bond Pharmacy did not start in-house environmental monitoring until on or about 7/30/2015, more than 5 months after your firm started production.

- On 9/14/2015, gaps were observed around the perimeter of the pass through door from an unclassified area leading into the ISO 7 area.

- According to your firm's SOP, AIS-PHA-408: "Gloved Fingertip Sampling", all new compounding personnel (compounding technicians, as well as, all pharmacist, regardless, of whether they physically perform the duties of compounding or they supervise compounding) must successfully complete 3 Gloved Fingertip sampling occurrences prior to compounding CSPs for human use. For low/medium risk level compounding, subsequent gloved fingertip sampling will occur annually.
  - Documentation provided by your firm indicates one pharmacy technician completed gloved fingertip sampling on 10/20/2015, 8 1/2 months after your firm became operational on 2/9/2015. Furthermore, on 9/14/2015, I observed 2 pharmacy technicians in your facility, only one pharmacy technician completed gloved fingertip sampling on 10/20/2015.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	June P. Page, Investigator Marvin D. Jones, Investigator	10/27/2015

Supplemental #2
June 15, 2018
11:27 A.M.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	09/14/2015 - 10/27/2015 FEI NUMBER 3011469631

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Charles R. Bell, Founder and President, COO

FIRM NAME	STREET ADDRESS
Advanced Infusion Solutions	132 Fairmont St Ste B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Clinton, MS 39056-4721	Producer of Sterile Products

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically,

- Per your firm's SOP, AIS-PHA-404: "Hand Hygiene and Garbing", section 4.3.5 describes hand washing will be performed for at least 30 seconds.
  - On 9/14/2015, a pharmacy technician was observed washing their hands in anteroom for approximately 10 seconds and drying their hands with a non-sterile disposable cloth.

- According to your firm's SOP, AIS-PHA-404: "Hand Hygiene and Garbing", section 4.4.9, gloved hands will be sprayed with sterile 70% IPA prior to entering the ISO 5 area and anytime the employee's hand re-enters the ISO 5 area.
  - On 9/14/2015, a pharmacy technician was observed placing the outer covering of a 0.9% NaCl 1000-mL bag into the trash receptacle in the ISO 7 area and returning to the ISO 5 area without sanitizing their gloves.

OBSERVATION 3

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

- Per your firm's SOP, AIS-PHA-404: "Hand Hygiene and Garbing", section 4.3.8 states to don a clean, lint free cover garment (Tyvek or equivalent) with sleeves that fit snugly around the wrists and which securely encloses the neck. In addition, section 4.3.10 of the aforementioned SOP, states to fasten the closures of the gown completely.
  - On 9/14/2015, a pharmacy technician was observed wearing a non-sterile gown that was open, exposing their street clothes to the sterile environment.

- Per your firm's SOP, AIS-PHA-404: "Hand Hygiene and Garbing" , section 4.5.1.3, gowns may be saved for subsequent use during the same shift/day and must be hung on a hook on the clean side of the anteroom.
  - On 9/14/2015, a pharmacy technician was observed dragging their gown on the floor of the anteroom from the clean side to the dirty side and then hung up the gown on the dirty side of the anteroom to be reused.
  - On 9/14/2015, another pharmacy technician was observed entering the anteroom from the buffer room, and then hung their gown on the dirty side of the anteroom for subsequent use.

- The gowning components your firm uses during aseptic processing are not sterile. The gowns, hair covers, face masks, and shoe covers are stored in an unclassified area. Furthermore, the gowns are stored in an open bag.
  - On 9/14/2015, a pharmacy technician was observed without a beard net and no eye protection while processing in the ISO 7 and ISO 5 areas.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	June P. Page, Investigator Marvin D. Jones, Investigator	10/27/2015

Supplemental #2
June 15, 2018
11:27 A.M.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	09/14/2015 - 10/27/2015
	FEI NUMBER 3011469631

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Charles R. Bell, Founder and President, COO

FIRM NAME	STREET ADDRESS
Advanced Infusion Solutions	132 Fairmont St Ste B
CITY, STATE, ZIP CODE, COUNTRY Clinton, MS 39056-4721	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Products

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

- In the ISO 7 area (Buffer Room), rust spots were observed on floor, ~~and filth~~ and residue streaks were observed on the walls. Your ISO 7 area is adjacent to your firm's ISO 5 area, where production occurs. Furthermore, no physical barrier distinguishes your firm's ISO 7 area from the ISO 5 area.

- According to the SOP, AIS-PHA-304: "Cleaning and Disinfecting of the Compounding Facility", cleaning will be performed in the ISO 5 area (VLAFW) prior to the beginning of each shift, immediately prior to each batch, every 30 minutes throughout the shift when ongoing drug production activities are occurring, after spills, and when microbial contaminations known to have been or is suspected of having been introduced.
  - Your firm provided a sample of the cleaning log for 9/14/2015 and a sample log from 7/10-16/2015 which shows daily cleaning only occurs at the beginning and end of the day.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	June P. Page, Investigator Marvin D. Jones, Investigator	10/27/2015

Supplemental #2
June 15, 2018
11:27 A.M.

Additional Correspondence

Supplemental #2
June 15, 2018
11:27 A.M.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	09/15/2015 - 10/27/2015
	FEI NUMBER 3011804748

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Charles R. Bell, Founder and President, COO

FIRM NAME	STREET ADDRESS
Bond Pharmacy, Inc. dba Advanced Infusion Solutions	623 Highland Colony Pkwy Ste 100
CITY, STATE, ZIP CODE, COUNTRY Ridgeland, MS 39157-6077	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

- On or about 7/10/2015, air and surface samples were collected and analyzed by Hayes Microbial Consulting. Results of these samples identified multiple organisms of bacteria and fungus in your firm's ISO 7 and ISO 8 areas. Your firm failed to conduct appropriate follow-up investigations. Your firm failed to provide documentation identifying the organisms or species for each colony growth.
  - On 7/17/2015, Hayes Microbial Consulting reported 6 air samples and 2 contact sample exceed, or found to be equal to, the limit of detection (1 CFU/M3):
    - An air sample was taken at location #37: Bacteria: Bacillus, Corynebacterium, Micrococcus, and Staphylococcus sp. were detected, exceeding the prescribed action level set forth in your firm's SOP, AIS-PHA-210: "Pharmacy Cleanroom Viable Air Sampling". The ISO 7 action level is >10, the Hayes microbial Consulting report documents 12 CFU's was recorded.
      - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #37 is in the middle of your firm's gown room (ISO 7 area).
      - On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplifi 797.
        - Your firm's in-house report indicates sampling occurred on the far W and E side of the gown room (ISO 7 area). This sampling location is not equivalent to sampling location #37 conducted by Hayes Microbial Consulting.
    - A contact sample was taken at location #46: Bacteria: Staphylococcus sp. was detected.
      - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #46 is your firm's staging area (ISO 8 area).
        - Your firm's documentation supporting in-house environmental contact plate sampling indicates sampling was not conducted in your firm's staging area.
    - A contact sample was taken at location #40: Bacteria: Staphylococcus sp. was detected.
      - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #40 is in the firm's anteroom - on the NE side of the door entrance

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	June P. Page, Investigator Marvin D. Jones, Investigator Debra A. Taylor, Investigator	10/27/2015

LISA T. MICHEL, ANALYST
Gary C Pace-Tr. Analyst

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

11:27 A.M.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	09/15/2015 - 10/27/2015 FEI NUMBER 3011804748

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Charles R. Bell, Founder and President, COO

FIRM NAME	STREET ADDRESS
Bond Pharmacy, Inc. dba Advanced Infusion Solutions	623 Highland Colony Pkwy Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ridgeland, MS 39157-6077	Producer of Sterile Products

from the unclassified area (ISO 8 area).

- Your firm's documentation supporting in-house environmental contact plate sampling indicates 3 sampling locations occurred on the SW side of the anteroom while 0 (zero) samples were taken on the NE side of the anteroom. These sampling location are not equivalent to sampling location #40 conducted by Hayes Microbial Consulting.

- An air sample was taken at location #35: Bacteria: Staphylococcus sp. was detected.
  - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #35 is your firm's stock solution room (ISO 7 area).
  - On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplifi 797.
    - Your firm's in-house report documents zero colonies were detected at location (5A) LAFW 40647 - Stock Solutions Room (ISO 5 area) and zero colonies were detected at location (4A) Stock Solutions Room. Your firm's in-house environmental monitoring locations was compared to your firm's 3rd party contractor's environmental monitoring locations. Upon comparison, it appears your firm's sampling location are not equivalent to the sampling location #35 conducted by Hayes Microbial Consulting.
- An air sample was taken at location #39: Bacteria: Bacillus, Micrococcus, and Staphylococcus sp. were detected.
  - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #39 is in the middle the firm's anteroom (ISO 8 area).
  - On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplifi 797.
    - Your firm's in-house report documents colony growth, 32 CFU's, in the ISO 8 anteroom - gown room door (ISO 8 area). This sampling location is not equivalent to sampling location #39 conducted by Hayes Microbial Consulting.
- An air sample was taken at location #41: Bacteria: Staphylococcus sp. was detected.
  - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #41 is your firm's cart pass thru area (ISO 8 area).
  - On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplifi 797.
    - Your firm's 7/17/2015 in-house report does not document sampling was conducted at this location.
- An air sample was taken at location #43: Bacteria: Staphylococcus sp. was detected.
  - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #43 is your firm's materials handling area (ISO 8 area).
  - On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplifi 797.
    - Your firm's 7/17/2015 in-house report does not document sampling was conducted at this location.
- An air sample was taken at location #45: Fungi: Cladosporium, unspecified mold. Bacteria: Bacillus, Micrococcus, and Staphylococcus sp. were detected.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	June P. Page, Investigator Marvin D. Jones, Investigator Debra A. Taylor, Investigator	10/27/2015

LISA T. MICHEL, ANALYST
Gary C Pecic Jr, Analyst GCP

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	09/15/2015 - 10/27/2015 FEI NUMBER 3011804748

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Charles R. Bell, Founder and President, COO

FIRM NAME	STREET ADDRESS
Bond Pharmacy, Inc. dba Advanced Infusion Solutions	623 Highland Colony Pkwy Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ridgeland, MS 39157-6077	Producer of Sterile Products

- According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #45 is your firm's staging area (ISO 8 area).
- On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplifi 797.
  - Your firm's 7/17/2015 in-house report does not document sampling was conducted at this location.

- Your firm's environmental monitoring data from July - October 2015, documents several instances indicating colony growth in your firm's ISO 5, ISO 7, and ISO 8 areas. However, your firm did not conduct adequate investigations assuring these areas are free from microbial contamination.

- Surface and air monitoring of the ISO 5 environment are not performed each day sterile drug products are produced. Your firm's current practice is to perform weekly surface and air monitoring. This is inadequate as environmental conditions are not monitored every day production occurs.

- Personnel monitoring is not performed each day sterile drug products are produced.

- Your firm's management stated in-house personnel monitoring is performed weekly. However, management did not provide documentation assuring your firm conducted personnel monitoring prior to the beginning the production of sterile drug products on 2/10/2014 through 6/4/2015.

- According to your firm's SOP, AIS-PHA-408: "Gloved Fingertip Sampling", all new compounding personnel (compounding technicians, as well as, all pharmacist, regardless, of whether they physically perform the duties of compounding or they supervise compounding) must successfully complete 3 Gloved Fingertip sampling occurrences prior to compounding CSPs for human use. For high risk level compounding, subsequent gloved fingertip sampling will occur semi-annually.
  - On 9/15/2015, I observed 2 stock solution pharmacists actively compounding stock solutions of 6 - 600mL bags of Morphine 62.5 mg/mL and 5 - 200mL bags of Fentanyl 10 mg/mL. Your firm did not provide personnel monitoring data for the stock solution pharmacist for 2015.
  - In addition, your firm did not provide documentation supporting fingertip monitoring was conducted for all pharmacists I observed actively compounding in your facility on 9/15/2015.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

- On 9/15/2015, a HEPA filter (ISO 5 area) appeared dirty; a thermaplate (ISO 7 area) used for compounding appeared

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	June P. Page, Investigator Marvin D. Jones, Investigator Debra A. Taylor, Investigator	10/27/2015

Usact. Michel, Analyst
Gary C. Recic Jr, Analyst GCP

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	09/15/2015 - 10/27/2015
	FEI NUMBER 3011804748

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Charles R. Bell, Founder and President, COO

FIRM NAME	STREET ADDRESS
Bond Pharmacy, Inc. dba Advanced Infusion Solutions	623 Highland Colony Pkwy Ste 100
CITY, STATE, ZIP CODE, COUNTRY Ridgeland, MS 39157-6077	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Products

dirty; several storage bins containing sterile components, located directly under the ISO 5 hood, appeared to have residue from splatter or spills; a trash receptacle (ISO 7 area) appeared dirty.

- On 9/15/2015, a stock solution compounding pharmacist was observed improperly cleaning the LAFW prior to performing aseptic bulk compounding of fentanyl. The pharmacist sprayed 70% Sterile IPA directly on a sterile disposable cloth and wiped the workbench in a circular fashion, moving from front to back.

OBSERVATION 3

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,

- Your firm's SOP, AIS-PHA-412: Conduct of Personnel in Controlled Areas and Aseptic Technique Overview, section 7.12 states Area Clearance: is an activity that ensures that only <u>one</u> "batch" is present at a compounding workstation to avoid error and mix-ups of the components and labels from which the CSP is being prepared.
  - On 9/15/2015, a pharmacist was observed pulling from 7 different stock medications in one ISO 5 hood.
  - On 9/15/2015, multiple unlabeled syringes from different stock solutions, for multiple patients, were observed lying on a cart waiting to be compounded.
  - On 9/15/2015, multiple pharmacists were observed holding two separate prescriptions for two different patients, all syringes are unlabeled.
  - On 9/15/2015, powdered APIs were observed being weighed and staged, uncovered, in the ISO 7 area. The unlabeled, uncovered powder APIs were placed on a staging cart with multiple unlabeled syringes before being brought to the ISO 5 area.
  - On 9/15/2015, we observed multiple unlabeled compounded patient specific medications were placed in a hot water bath.

OBSERVATION 4

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

- Your firm's stock solutions undergo endotoxin testing one time prior to processing. However, your stock solutions are punctured multiple times during processing over several days. Your firm's stock solutions, at time of use, is not representative of the endotoxin testing conducted prior to processing.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	June P. Page, Investigator Marvin D. Jones, Investigator Debra A. Taylor, Investigator	10/27/2015

LISA T. MICHEL, Analyst
Gary C. Peace Jr., Analyst GCP

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

11:27 A.M.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax: (615) 366-7802 Industry Information: www.fda.gov/oc/industry	09/15/2015 - 10/27/2015 FEI NUMBER 3011804748

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Charles R. Bell, Founder and President, COO

FIRM NAME	STREET ADDRESS
Bond Pharmacy, Inc. dba Advanced Infusion Solutions	623 Highland Colony Pkwy Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ridgeland, MS 39157-6077	Producer of Sterile Products

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically,

- On 9/15/2015, a pharmacist was observed crossing into the clean side of the anteroom with no shoe cover over their street shoes.
- On 9/15/2015, a pharmacist was observed reaching under the ISO 5 workbench to gather supplies to continue aseptic processing 24 times without sterilizing their gloves or the components entering ISO 5 area form a dirtier area.
- On 9/15/2015, a pharmacist compounding a stock solution of fentanyl was observed leaving the ISO 5 area, entering the ISO 7 area, and returning to the ISO 5 area 13 times before sanitizing their gloves.
- On 9/15/2015, multiple pharmacists were observed with their heads under the ISO 5 hood.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	June P. Page, Investigator Marvin D. Jones, Investigator Debra A. Taylor, Investigator	10/27/2015

Lisa T. Michel, Analyst
Gary C. Peck Jr., Analyst

Supplemental #2
June 15, 2018
11:27 A.M.

HUNTON & WILLIAMS

HUNTON & WILLIAMS LLP
2200 PENNSYLVANIA AVENUE, NW
WASHINGTON, D.C. 20037-1701

TEL 202 • 955 • 1500
FAX 202 • 778 • 2201

SHELDON T. BRADSHAW
DIRECT DIAL 202 • 955 • 1575
EMAIL sbradshaw@hunton.com

FILE NO. 86160.000003

VIA OVERNIGHT MAIL

November 20, 2015

Ms. Ruth P. Dixon
District Director, New Orleans District
U.S. Food and Drug Administration
404 BNA Drive, Building 200, Suite 500
Nashville, TN 37217-2597

Re: Posting AIS' 483 Responses to ORA's Electronic Reading Room

Dear Ms. Dixon:

On behalf of Advanced Infusion Solutions ("AIS"), we authorize the United States Food and Drug Administration ("FDA") to publicly disclose the information described below on FDA's website. Specifically, we ask that the information described below be posted in ORA's electronic reading room next to the links to the two Form 483s issued to AIS on October 27, 2015.

Information to be disclosed: Letter from Sheldon Bradshaw, Hunton & Williams LLP to Ruth Dixon, District Director, New Orleans District dated November 16, 2015 and Attachment A (excluding exhibits 1 and 2) and Attachment B (excluding exhibits 1 and 2). Attachments A and B contain AIS' responses to the two FDA Form 483s dated October 27, 2015.

AIS understands that the information that is disclosed may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 3310 and 5 U.S.C. § 552(b)(4) that is exempt from public disclosure under these statutory provisions and/or relevant FDA regulations. AIS agrees to hold FDA harmless for any injury caused by FDA's sharing the information with the public.

Sincerely,

Sheldon T. Bradshaw (/sbc)

Sheldon T. Bradshaw

cc: Charles R. Bell, Jr.
President & Founder
Advanced Infusion Solutions

HUNTON
WILLIAMS

HUNTON & WILLIAMS LLP
2200 PENNSYLVANIA AVENUE, NW
WASHINGTON, D.C. 20037-1701

TEL 202 • 955 • 1500
FAX 202 • 778 • 2201

SHELDON T. BRADSHAW
DIRECT DIAL: 202 • 955 • 1575
EMAIL: sbradshaw@hunton.com

FILE NO: 86160.000002

November 16, 2015

CONFIDENTIAL

Via Overnight Mail

Ms. Ruth P. Dixon
District Director, New Orleans District
U.S. Food and Drug Administration
404 BNA Drive, Building 200, Suite 500
Nashville, TN 37217-2597

Re: Inspectional Observations at AIS Facilities; FEI Nos. 3011804748 and 3011469631

Dear Ms. Dixon,

I am writing on behalf of my client, Advanced Infusion Solutions ("AIS"), in regards to the Form FDA 483s issued by Food and Drug Administration ("FDA" or "Agency") investigators to AIS' compounding pharmacies located in Clinton, Mississippi and Ridgeland, Mississippi on October 27, 2015. Attached please find my client's responses to the inspectional observations contained in the FDA 483s.[1] As an organization, AIS is fully committed to complying with all applicable regulatory requirements. While AIS appreciates the opportunity to respond to the inspectional observations contained in the 483s, I write separately to address the questionable legal and regulatory foundation for the observations.

As an initial matter, if FDA releases either of the FDA 483s (either to specific individuals/ entities or more broadly to the general public), basic fairness demands that FDA also release AIS' responses to the FDA 483s, including this letter. Releasing the FDA 483s alone would, at best, leave the reader with an incomplete and misleading picture of AIS' compounding practices. Indeed, in light of the inspectional observations, patients and physicians may be left with the false impression that AIS is compounding drug products under insanitary conditions when, in fact, AIS operates in compliance with Chapter 797 of the U.S. Pharmacopeia ("USP Chapter 797"), which sets forth the standards governing the compounding of sterile injectables. Sterile medications compounded by AIS are safe and appropriate for patients to use, which patients and physicians will not fully appreciate if FDA selectively releases the 483s without AIS' responses to the same.

[1] *See* Attachment A (Ridgeland 483 Response), and Attachment B (Clinton 483 Response).

HUNTON & WILLIAMS

As you are aware, AIS is regulated under Section 503A of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). AIS is a specialty compounding pharmacy that is engaged exclusively in the practice of traditional pharmacy compounding, i.e., AIS only compounds unique medications for identified individual patients pursuant to a valid prescription issued by a licensed prescriber. Unlike pharmacies operating as outsourcing facilities under Section 503B of the FD&C Act, pharmacies operating under Section 503A are exempt from FDA's current good manufacturing practice ("cGMP") regulations.[2] Instead, 503A pharmacies must comply with state laws and regulations, which, for pharmacies engaged in compounding sterile injectables, typically includes the requirements set forth in USP Chapter 797.

The FDA 483 inspectional observations do not specifically cite FDA's cGMP regulations, nor, curiously, do they cite any rule or regulation actually enforced by FDA. Instead (and, again, without citing the FD&C Act or any regulation promulgated by FDA), the FDA 483s tacitly imply that AIS is compounding drugs "under insanitary conditions" in violation of Section 501(a)(2)(A) of the FD&C Act. Interestingly, however, the inspectional observations primarily identify practices that FDA has previously identified as failing to comply with FDA's cGMP regulations. In practical effect, therefore, the 483 inspectional observations suggest that AIS' compounded drugs are compounded "under insanitary conditions"[3] *because* they are not compounded "in conformity with" FDA's stringent cGMP requirements.[4]

FDA cannot lawfully conclude that a drug compounded under Section 503A was compounded "under insanitary conditions" in violation of Section 501(a)(2)(A) simply *because* it was not compounded "in conformity with" cGMP requirements in violation of Section 501(a)(2)(B).[5] An inspection classification of Official Action Indicated ("OAI")—or any other agency action—based on such a conclusion would be contrary to the FD&C Act and FDA guidance documents. Again, drug products that are compounded under section 503A are not required to be compounded in conformity with cGMP requirements—under the FD&C Act, they are exempt

---

[2] *Compare* FD&C Act § 503A(a) (exempting traditional compounding pharmacies from cGMP requirements), *with id.* § 503B(a) (applying cGMP requirements to outsourcing facilities).

[3] *Id.* § 501(a)(2)(A).

[4] *Id.* § 501(a)(2)(B).

[5] *Compare id.* § 501(a)(2)(A) (concerning adulteration caused by "insanitary conditions whereby [a drug] may have been contaminated with filth"), *with id.* § 501(a)(2)(B) (concerning adulteration caused by failing to operate "in conformity with" cGMPs).

HUNTON& WILLIAMS

from Section 501(a)(2)(B), which states that a drug is adulterated if it is not compounded in conformity with cGMP requirements.[6] By definition, a drug compounded under Section 503A cannot be deemed to be adulterated because it was not compounded in conformity with cGMPs.

To be sure, drugs compounded under section 503A may be deemed to be adulterated if they were, in fact, truly compounded "under insanitary conditions whereby [they] may have been contaminated with filth"—but FDA cannot interpret that adulteration provision so as to create a presumption that a drug not compounded in conformity with FDA's cGMPs is, by definition, compounded under insanitary conditions whereby it may have been contaminated with filth. Section 501(a)(2)(A) (concerning adulteration caused by "insanitary conditions whereby [a drug] may have been contaminated with filth") and section 501(a)(2)(B) (concerning adulteration caused by failing to operate "in conformity with" cGMPs) must be given independent meaning. It is an "elementary canon of construction that a statute should be interpreted so as not to render one part inoperative."[7]

Moreover, federal agencies "cannot interpret federal statutes to negate their own stated purposes."[8] FDA cannot conclude that drugs compounded under section 503A that were not compounded in conformity with cGMPs have, as a result, been compounded under insanitary conditions whereby they may have been contaminated with filth. Such a conclusion would render either section 501(a)(2)(A) or section 501(a)(2)(B) superfluous, as both adulteration sections would regulate the same conduct. There would be no distinction between adulteration due to insanitary conditions whereby a drug may have been contaminated with filth and adulteration due to a failure to operate in conformity with cGMPs—notwithstanding the fact that these two types of adulteration appear in different sections, *one of which the FD&C Act expressly precludes from applying to drugs compounded under section 503A.*

Indeed, FDA cannot circumvent the statutory exemption from cGMP requirements for drugs compounded under Section 503A by conflating the two adulteration provisions found in Section

---

[6] *See id.* § 503A(a) (stating that Section 501(a)(2)(B) "shall not apply" to drugs compounded under Section 503A); *see also* FDA, Guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act* § IV(A) (July 2014) [hereinafter "*503A Compounding Guidance*"] (not listing compliance with cGMPs among the requirements that are applicable to compounded drugs that meet the conditions of section 503A).

[7] *Colautti v. Franklin*, 439 U.S. 379, 392 (1979).

[8] *New York State Dept. of Social Servs. v. Dublino*, 413 U.S. 405, 419-20 (1973).

HUNTON WILLIAMS

501(a)(2)(A) (concerning adulteration caused by "insanitary conditions whereby [a drug] may have been contaminated with filth") and Section 501(a)(2)(B) (concerning adulteration caused by failing to operate "in conformity with" cGMPs). A stated purpose of the Food and Drug Administration Modernization Act of 1997,[9] which added section 503A to the FD&C Act, was to exempt drugs compounded under section 503A from cGMP requirements.[10] This purpose would be "negated" if FDA could determine that drugs compounded under section 503A that are not produced in conformity with cGMPs are, as a result, compounded under insanitary conditions whereby they may have been contaminated with filth. Such an interpretation of the FD&C Act would effectively nullify the statutory exemption.

Without conceding that FDA has the statutory authority to regulate the practice of pharmacy, FDA should recognize that drug products compounded under Section 503A are not compounded under insanitary conditions whereby they may have been contaminated with filth if they are compounded in compliance with applicable USP requirements. AIS takes great satisfaction in compounding sterile injectables in compliance with state pharmacy law, which in many states incorporates USP Chapter 797 (National Formulary General Chapter <797> Pharmaceutical Compounding—Sterile Preparations). Drug products compounded under Section 503A that have been compounded in compliance with USP Chapter 797 simply are not adulterated under Section 501(a)(2)(A). To the contrary, a drug compounded in compliance with USP Chapter 797 has been compounded using methods that prevent the level of contamination implicated by the "insanitary conditions whereby it may have been contaminated with filth" adulteration section.

Section 501(a)(2)(A) describes a type of adulteration (i.e., adulteration caused by "insanitary conditions whereby [a drug] may have been contaminated with filth") that is characterized by a *significant* level of contamination or potential contamination. Indeed, the statutory term "insanitary conditions" is modified and limited by the statutory phrase "whereby it may have been contaminated *by filth* (emphasis added)." The meaning of a statutory term, like "insanitary," may be determined "by the company it keeps,"[11] i.e., "by reference to the meaning

---

[9] Pub. L. 105-115.

[10] *See 503A Compounding Guidance* § II (stating that "[s]ection 503A describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from . . . section 501(a)(2)(B) (concerning current good manufacturing practice)").

[11] *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995); *see also Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961) ("The maxim *noscitur a sociis*, that a word is known by the company it keeps, . . . is often wisely applied

HUNTON& WILLIAMS

of words associated with it."[12] Insanitary conditions, therefore, can be determined by reference to the term "filth," which in common usage means "offensive or disgusting dirt or refuse; foul matter."[13] Synonyms of "filth" include "dirt, refuse, pollution, muck, shit (taboo slang), crap (taboo slang), garbage, sewage, contamination, dung, sludge, squalor, grime, feces, slime, excrement, nastiness, carrion, excreta, crud (slang), foulness, putrefaction, ordure, defilement, kak (S. African taboo slang), grot (slang), filthiness, uncleanness, putrescence, foul matter."[14] Numerous cases interpreting the term "filth" describe egregious levels of contamination or potential contamination, including, characteristically, the presence of animal droppings.[15]

A drug compounded *in compliance with USP Chapter 797* could not, by definition, ever have the level of contamination or potential contamination sufficient to meet the adulteration standard established in section 501(a)(2)(A). If, in fact, a compounding pharmacy complies with the requirements of USP Chapter 797, then the drugs compounded by that pharmacy will not have been produced under "insanitary conditions whereby [they] may have been contaminated with filth." Accordingly, FDA should determine—as a matter of law and enforcement policy—that a drug compounded under section 503A is not adulterated due to insanitary conditions if the drug was compounded in compliance with USP Chapter 797.

AIS compounds drug products in compliance with USP Chapter 797, as evidenced by its exemplary history of compliance with well-established pharmacy rules and regulations. Since AIS' compounding pharmacy first opened in December of 2008, its compliance with USP Chapter 797 has been annually documented in numerous inspections by multiple states and third-

---

where a word is capable of many meanings in order to avoid the giving of unintended breadth to the Acts of Congress.").

[12] *Neal v. Clark*, 95 U.S. 704, 708 (1877) ("It is a familiar rule in the interpretation of . . . statutes that a passage will be best interpreted by reference to that which precedes and follows it" (quotation omitted).).

[13] *See* Dictionary.com (last visited Nov. 4, 2015), *available at* http://dictionary.reference.com/browse/filth.

[14] The Free Dictionary (last visited Nov. 4, 2015), *available at* http://www.thefreedictionary.com/filth.

[15] *See, e.g.*, *United States v. Am. Mercantile Corp.*, 889 F.Supp.2d 1058, 1062-63 (W.D. Tenn. 2012) ("FDA laboratory analysis confirmed the presence of filth, including rodent and insect filth, in the samples collected before and after cleaning."); *United States v. Gel Spice Co.*, 601 F.Supp. 1205, 1211 (E.D.N.Y. 1984) (holding that "laboratory analysis and graphic photographs" proved that food stored with rodent hairs, rodent excreta pellets, mammalian urine, and dead and decaying rodents was "held under conditions whereby it may have become adulterated with filth"); *United States v. H.B. Gregory Co.*, 502 F.2d 700, 703 (7th Cir. 1974) (describing filthy conditions that included "numerous rodent excreta pellets and multiple rodent urine stains, as well as . . . other general insanitary conditions"); *United States v. Cassaro, Inc.*, 443 F.2d 153, 154 (1st Cir. 1971) (holding that "[i]nsects and larvae fragments have been held to constitute 'filth' in numerous cases.").

HUNTON& WILLIAMS

party consultants. Notably, over the course of the last seven years, AIS has dispensed hundreds of thousands of sterile injectable drug products, yet it has never had sterility-related issues with any of its drug products that has required any remedial action, including recalls, nor has AIS ever had any sterility issues that caused any patient harm.

If compliance with USP Chapter 797 does not ensure that a drug compounded under Section 503A is not compounded under insanitary conditions in violation of Section 501(a)(2)(A), then the standards by which a compounding pharmacy operating under Section 503A must operate are completely opaque. For example, one inspectional observation objects to AIS' practice of conducting *weekly* instead of *daily* environmental monitoring of its cleanroom. AIS' *weekly* environmental monitoring exceeds that required by USP Chapter 797, which only requires that environmental monitoring be conducted semiannually.[16] While FDA's cGMP regulations may require *daily* environmental monitoring of aseptic drug manufacturing,[17] it cannot be (as noted above) that a compounding pharmacy operating under Section 503A must comply with those regulations in order to ensure that its compounded drug products are not compounded "under insanitary conditions whereby [they] may have been contaminated with filth," since such pharmacies are exempt from cGMPs.[18]

Notably, specific standards for ensuring that drugs compounded under Section 503A are not compounded under insanitary conditions (e.g., daily environmental monitoring) cannot be found in any FDA publication. Industry, apparently, must learn to divine the minds of Agency personnel to ascertain the applicable standards. However, as the U.S. Court of Appeals for the Seventh Circuit specifically reminded FDA, standards are not binding on industry if they can be found "just in the oral testimony of an agency employee."[19] As the Court made clear, the

---

[16] *See* USP Chapter 797 ("Air sampling shall be performed at least semiannually (i.e., every 6 months) as part of the re-certification of facilities and equipment.").

[17] *See* FDA, Guidance for Industry, *Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice* § X.A.1 (Sep. 2004) (stating that, per cGMPs, the "timing, frequency, and location" of environmental monitoring "should be carefully selected based upon their relationship to the operation performed"); *see also id.* (providing that "[a]ll environmental monitoring locations should be described in SOPs," which also "should also address . . . frequency of sampling"); *see also id.* App. 1, § F (stating that an "environmental monitoring program should be established that routinely ensures acceptable microbiological quality of air, surfaces, and gloves," and that "[a]ir quality should be monitored periodically during each shift").

[18] *See* FD&C Act § 503A(a).

[19] *United States v. Farinella*, 558 F.3d 695, 699 (7th Cir. 2009).

HUNTON & WILLIAMS

standard cannot be "some bureaucrat's secret understanding of the law. 'The idea of secret laws is repugnant. People cannot comply with laws the existence of which is concealed.'"[20]

The Supreme Court has made it clear that regulated parties are not expected to "divine the agency's interpretations" of its rules in advance of the agency announcing such interpretations.[21] An attempt to impose cGMP requirements, or to enforce standards relating to a never-before-announced interpretation of the "insanitary conditions" adulteration provision, on a 503A compounding pharmacy through observations in an FDA 483 would violate principles of the well-established Fair Notice Doctrine. Additionally, the imposition of new and previously unannounced standards would constitute rulemaking under the Administrative Procedure Act ("APA") while skirting the notice-and-comment requirement that the APA requires agencies to follow.[22] Critically, FDA has never announced that compliance with USP Chapter 797 standards by a 503A compounding pharmacy is insufficient to meet the FD&C Act's requirement that drugs not be compounded under insanitary conditions. Accordingly, absent specific written standards for pharmacies to follow, it must be that sterile drug products compounded under Section 503A are not compounded under insanitary conditions whereby they may have been contaminated with filth if they are compounded in compliance with USP Chapter 797.

We would further note that FDA's inspection of AIS' pharmacies greatly exceeded the Agency's inspectional authority. Although FDA may have the authority to inspect a 503A compounding pharmacy to confirm that it is operating within the parameters set forth in Section 503A of the FD&C Act, its authority to inspect pharmacies that operate in conformance with applicable local (state) laws is limited.[23] Indeed, although the overwhelming majority of the practices identified by the FDA investigators were, in fact, fully compliant with state law, including USP Chapter 797, we would further emphasize that even if the identified practices were inconsistent with state law (and left uncorrected), it would be inappropriate to include them as observations in an FDA 483. Specifically, while Section 503A requires that compounding pharmacies use ingredients that "comply with the standards of an applicable United States Pharmacopoeia . . . monograph,"

---

[20] *Id.* (quoting *Torres v. INS*, 144 F.3d 472, 474 (7th Cir. 1998)).

[21] *Christopher v. Smithkline Beecham Corp.*, 132 S.Ct. 2156, 2168 (2012) ("It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference.")

[22] *See* 5 U.S.C. § 553.

[23] *See* 21 U.S.C. § 374 (2)(a).

HUNTON& WILLIAMS

there is no general requirement under Section 503A that a pharmacy's compounding practices comply with USP Chapter 797. Instead, that requirement is imposed by state law. As a result, the practices in question are a matter of state (rather than federal) law.

Finally, AIS is confident that its processes result in the production of compounded products that are safe and appropriate for use by its patients. Accordingly, AIS allowed FDA's investigators to review its systems and processes, unaware that those investigators would attempt to hold AIS to undefined and inapplicable standards and make unfounded allegations of "insanitary conditions." AIS denies that its products are adulterated by any standard, and the company specifically rejects the notion that compliance with USP Chapter 797 could support observations that its products were compounded "under insanitary conditions whereby [they] may have been contaminated with filth."

AIS welcomes the opportunity to answer any questions you may have. To that end, we request a meeting with you to discuss this letter and AIS' responses to the FDA 483 inspectional observations as soon as possible. In light of the significant legal issues raised by the FDA 483, we respectfully request that officials from FDA's Office of the Chief Counsel be invited to attend the meeting. Because it is our understanding that the inspection was part of an initiative overseen by the Compounding and Pharmacy Practices Branch ("CPPB") in the Office of Compliance at the Center for Drug Evaluation and Research, we request that the appropriate representatives from CPPB be invited to participate as well.

Sincerely,

Sheldon Bradshaw by KS

Sheldon T. Bradshaw

Attachments

cc: Amanda Edmonds (via e-mail)
Deputy Chief Counsel
Office of the Chief Counsel
U.S. Food and Drug Administration

ATTACHMENT A

CONFIDENTIAL

Via Overnight Mail

November 16, 2015

Ms. Ruth P. Dixon
District Director, New Orleans District
404 BNA Dr., Bldg. 200, Suite 500
Nashville, TN 37217-2597

Re: Response to Inspectional Observations – FEI Number 3011804748

Dear Ms. Dixon,

Please accept this correspondence in response to the FDA Form 483 provided to Advanced Infusion Solutions' ("AIS") facility in Ridgeland, Mississippi on October 27, 2015. As an organization, AIS is committed to complying with all applicable regulatory requirements. We appreciate the opportunity to respond to the inspectional observations contained in the 483. For ease of reference, the inspectional observations are repeated in bold text and our responses are set forth below each observation.

While AIS believes its practices are in compliance with applicable regulatory requirements, including USP <797>, AIS views the FDA's 483 process as an opportunity for improvement. AIS has used this process to inquire, evaluate, bolster, and re-approach its entire quality assurance program, including but not limited to the ongoing engagement of a third-party consultant (CV attached as Exhibit 1) and the retention of a Director of Quality.

Since its inception, AIS has been committed to improving performance by implementing pharmacy best practices and the USP <797> standards in sterile compounding. AIS recognizes the value of the USP <797> observations that FDA has brought to AIS's attention. Based on the FDA inspector's observations and USP <797> standards, corrective and preventive action (CAPA) plans and Key Performance Indicators (KPIs) were developed immediately to correct any observations, as well as to prevent recurrence of any future deviations from USP <797> standards. For AIS, quality improvement will continue with management monitoring the effectiveness of the KPIs using established audit tools.

The AIS leadership team has assigned managers as observers to conduct unannounced random audits in established frequencies to make sure that the compounding staff are strictly following the USP <797> standards. All observations (sufficient or insufficient) are documented and reviewed by the Pharmacist-in-Charge or a member of the senior leadership team. Any insufficient observations are addressed immediately and handled through remedial retraining/re-

education. Any insufficient observations are reevaluated and documented within 48 hours. All KPI-related findings are presented to AIS senior leadership to evaluate the effectiveness of the program.

For the AIS pharmacy location referenced above, based on the FDA inspectors' observations and the USP <797> standards, the leadership team has identified 11 KPI metrics in the areas of aseptic garbing, aseptic technique, cleanroom state of control, and the sterile product integrity. The KPI metrics began on 09/28/15. AIS will continue to audit and report these observations to the leadership team based on the established audit tool frequencies for each specific KPI (weekly, biweekly and monthly). The KPI dashboard from Ridgeland is attached as Exhibit 2.

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

- **On or about 7/10/2015, air and surface samples were collected and analyzed by Hayes Microbial Consulting. Results of these samples identified multiple organisms of bacteria and fungus in your firm's ISO 7 and ISO 8 areas. Your firm failed to conduct appropriate follow-up investigations. Your firm failed to provide documentation identifying the organisms or species for each colony growth.**

- **On 7/17/2015, Hayes Microbial Consulting reported 6 air samples and 2 contact sample exceed, or found to be equal to, the limit of detection (1 CFU/M3):**

  - **An air sample was taken at location #37: Bacteria: Bacillus, Corynebacterium, Micrococcus, and Staphylococcus sp. were detected, exceeding the prescribed action level set forth in your firm's SOP, AIS-PHA-210: "Pharmacy Cleanroom Viable Air Sampling". The ISO 7 action level is> 10, the Hayes microbial consulting report documents 12 CFU's was recorded.**

    - **According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #37 is in the middle of your firm's gown room (ISO 7 area).**

    - **On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplify 797.**

      - **Your firm's in-house report indicates sampling occurred on the far W and E side of the gown room (ISO 7 area). This sampling location is not equivalent to sampling location #37 conducted by Hayes Microbial Consulting.**

  - **A contact sample was taken at location #46: Bacteria: Staphylococcus sp. was detected.**

- **According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #46 is your firm's staging area (ISO 8 area).**
    - **Your firm's documentation supporting in-house environmental contact plate sampling indicates sampling was not conducted in your firm's staging area.**

- **A contact sample was taken at location #40: Bacteria: Staphylococcus sp. was detected.**
    - **According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #40 is in the firm's anteroom- on the NE side of the door entrance from the unclassified area (ISO 8 area).**
        - **Your firm's documentation supporting in-house environmental contact plate sampling indicates 3 sampling locations occurred on the SW side of the anteroom while 0 (zero) samples were taken on the NE side of the anteroom. These sampling location are not equivalent to sampling location #40 conducted by Hayes Microbial Consulting.**

- **An air sample was taken at location #35: Bacteria: Staphylococcus sp. was detected.**
    - **According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #35 is your firm's stock solution room (ISO 7 area).**
    - **On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplify 797.**
        - **Your firm's in-house report documents zero colonies were detected at location (5A) LAFW 40647-Stock Solutions Room (ISO 5 area) and zero colonies were detected at location (4A) Stock Solutions Room. Your firm's in-house environmental monitoring locations was compared to your firm's 3rd party contractor's environmental monitoring locations. Upon comparison, it appears your firm's sampling location are not equivalent to the sampling location #35 conducted by Hayes Microbial Consulting.**

- **An air sample was taken at location #39: Bacteria: Bacillus, Micrococcus, and Staphylococcus sp. Were detected.**
    - **According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #39 is in the middle the firm's anteroom (ISO 8 area).**

- On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplify 797.
    - Your firm's in-house report documents colony growth, 32 CFU's, in the ISO 8 anteroom- gown room door (ISO 8 area). This sampling location is not equivalent to sampling location #39 conducted by Hayes Microbial Consulting.

- An air sample was taken at location #41: Bacteria: Staphylococcus sp. was detected.
    - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #41 is your firm's cart pass thru area (ISO 8 area).
    - On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplify 797.
        - Your firm's 7/17/2015 in-house report does not document sampling was conducted at this location.

- An air sample was taken at location #43: Bacteria: Staphylococcus sp. was detected.
    - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #43 is your firm's materials handling area (ISO 8 area).
    - On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplify 797.
        - Your firm's 7/17/2015 in-house report does not document sampling was conducted at this location.

- An air sample was taken at location #45: Fungi: Cladosporium, unspecified mold. Bacteria: Bacillus, Micrococcus, and Staphylococcus sp. were detected.
    - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #45 is your firm's staging area (ISO 8 area).
    - On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplify 797.
        - Your firm's 7/17/2015 in-house report does not document sampling was conducted at this location.

- Your firm's environmental monitoring data from July- October 2015, documents several instances indicating colony growth in your firm's ISO 5, ISO 7, and ISO 8

areas. However, your firm did not conduct adequate investigations assuring these areas are free from microbial contamination.

Based on USP <797> standards, AIS does not agree that its system for monitoring environmental conditions is deficient or poses any risk of harm to the public. Moreover, this observation fails to identify any applicable standard that AIS is alleged to have violated. AIS operates in strict compliance with USP <797>, and tests its systems, processes, and equipment regularly in accordance with USP <797> standards. Although our objective is no microbial growth in aseptic processing environments, AIS disagrees with the premise that an aseptic environment must at all times be free of microbial growth in order to safely produce CSPs.

USP <797> states, "Air sampling shall be performed at least semiannually (i.e., every 6 months) as part of the re-certification of facilities and equipment," and "Surface sampling shall be performed in all ISO classified areas on a periodic basis." As a pharmacy that dispenses high risk CSPs, AIS exceeds this USP <797> standard by performing weekly surface sampling and weekly viable air sampling. If any microbial growth is recovered during sampling activities, AIS uses Hayes Microbial Consulting, an appropriately-credentialed laboratory, to comply with the USP <797> requirement of identifying recovered microorganisms to at least the genus level.

USP <797> lists action levels for microbial growth recovered in classified environments. Please note the tables below for recommended action levels for viable air and surface sampling.

Table 2. Recommended Action Levels for Microbial Contamination*

†(cfu per cubic meter [1000 liters] of air per plate)

Classification	Air Sample†
ISO Class 5	> 1
ISO Class 7	> 10
ISO Class 8 or worse	> 100

* Guidance for Industry–Sterile Drug Products Produced by Aseptic Processing–Current Good Manufacturing Practice–US HHS, FDA September 2004.

Table 4. Recommended Action Levels for Microbial Contamination*

Classification	Fingertip Sample	Surface Sample (Contact Plate) (cfu per plate)
ISO Class 5	> 3	> 3
ISO Class 7	N/A	> 5
ISO Class 8 or worse	N/A	> 100

* Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products Annexes PE 009-6, 5 April 2007.

AIS reviews and trends all environmental sampling results in compliance with USP <797>. If *action levels* are exceeded, AIS cleans and disinfects the area within the cleanroom where actionable microbial growth is recovered. It is important to note that AIS not only cleans and disinfects the area of actionable microbial growth, but also the complete environment – and, many times, the complete room by the time sampling results are reviewed and documented (due to the required two- to seven-day incubation interval for the respective media type). This was the case in the above-referenced AirSafe (Hayes) report. AIS did not immediately receive the AirSafe (Hayes) report because it takes time for the vendor to analyze and document the testing results. During that time period, AIS cleaned and disinfected the entire cleanroom suite for several weeks upon receipt of the report.

If *actionable trends* are observed, AIS reevaluates "the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency with the aseptic compounding location," in compliance with USP <797>. As a continuous-quality organization,

AIS monitors and evaluates our aseptic processing environments and processes for actionable trends and corresponding improvement opportunities.

AirSafe, our vendor for controlled environment testing and certification, tests and certifies our cleanroom on a quarterly basis, exceeding the USP <797> semi-annual requirement. AIS has requested that AirSafe conduct surface sampling and viable air sampling semi-annually in conjunction with cleanroom recertification activities. This is done so that AIS can review the results obtained by a third-party vendor relative to our internal weekly results. Since no microbiological sampling plan can prove the absence of microbial contamination, and USP <797> states that sampling locations should be chosen "based on a risk assessment of compounding activities performed," AIS has not historically dictated the locations where AirSafe performs its environmental sampling. AIS will now ensure, however, that AirSafe synchronizes its surface and viable air sampling locations with AIS's environmental sampling plan, as you have recommended.

USP <1116>, an informational chapter of the U.S. Pharmacopeia, discusses the microbiological control and monitoring of aseptic processing environments. The chapter acknowledges the microbiological realities of aseptic processing in manned cleanrooms by stating: "In any environment where human operators are present, microbial contamination at some level is inevitable. Even the most cautious clean-room environment design and operation will not eliminate the shedding of microorganisms if human operators are present. Thus, an expectation of zero contamination at all locations during every aseptic processing operation is technically not possible and thus is unrealistic." AIS always gives suitable attention to its environmental monitoring results. USP <1116> provides appropriate perspective by stating: "Environmental monitoring is one of several key elements required in order to ensure that an aseptic processing area is maintained in an adequate level of control. Monitoring is a qualitative exercise, and even in the most critical applications such as aseptic processing, conclusions regarding lot acceptability should not be made on the basis of environmental sampling results alone."

AIS acknowledges the microbiological realities of aseptic processing in manned cleanrooms. In order to maintain a state of control within our aseptic processing pharmacy, AIS will continue to follow its current policy for weekly surface sampling and viable air sampling in compliance with USP <797>.

- **Surface and air monitoring of the ISO 5 environment are not performed each day sterile drug products are produced, Your firm's current practice is to perform weekly surface and air monitoring. This is inadequate as environmental conditions are not monitored every day production occurs.**

Daily environmental monitoring, including surface sampling and viable air sampling, is a cGMP requirement. As stated above, AIS conducts weekly surface sampling and viable air sampling. Of note, USP <1116> states: "Environmental monitoring is usually performed by personnel and thus requires operator intervention. As a result, environmental monitoring can both increase the risk of contamination and also give false-positive results. Thus, intensive monitoring is unwarranted, particularly in the ISO 5 environments that are used in the most critical zones of aseptic processing."

- **Personnel monitoring is not performed each day sterile drug products are produced.**

- **Your firm's management stated in-house personnel monitoring is performed weekly. However, management did not provide documentation assuring your firm conducted personnel monitoring prior to the beginning the production of sterile drug products on 2/10/2014 through 6/4/2015.**

- **According to your firm's SOP, AIS-PHA-408: "Gloved Fingertip Sampling", all new compounding personnel (compounding technicians, as well as, all pharmacist, regardless, of whether they physically perform the duties of compounding or they supervise compounding) must successfully complete 3 Gloved Fingertip sampling occurrences prior to compounding CSPs for human use. For high risk level compounding, subsequent gloved fingertip sampling will occur semi-annually.**

    - **On 9/15/2015, I observed 2 stock solution pharmacists actively compounding stock solutions of 6 - 600mL bags of Morphine 62.5 mg/mL and 5 - 200mL bags of Fentanyl 10 mg/mL. Your firm did not provide personnel monitoring data for the stock solution pharmacist for 2015.**

    - **In addition, your firm did not provide documentation supporting fingertip monitoring was conducted for all pharmacists I observed actively compounding in your facility on 9/15/2015.**

Daily environmental monitoring, including personnel monitoring, is a cGMP requirement. In the observation, FDA correctly states a section from our SOP governing Gloved Fingertip Sampling: "[A]ll new compounding personnel (compounding technicians, as well as, all pharmacists, regardless, of whether they physically perform the duties of compounding or they supervise compounding) must successfully complete 3 Gloved Fingertip sampling occurrences prior to compounding CSPs for human use. For high risk level compounding, subsequent gloved fingertip sampling will occur semi-annually." Please note that this policy is consistent with USP <797> requirements: "All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero CFU) no less than three times before initially being allowed to compound CSPs for human use." USP <797> also states: "After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel for this competency shall occur at least annually for personnel who compound low- and medium-risk level CSPs and semi-annually for personnel who compound high-risk level CSPs . . . ."

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

- **On 9/15/2015, a HEPA filter (ISO 5 area) appeared dirty; a thermaplate (ISO 7 area) used for compounding appeared dirty; several storage bins containing sterile**

components, located directly under the ISO 5 hood, appeared to have residue from splatter or spills; a trash receptacle (ISO 7 area) appeared dirty.

As discussed with FDA inspectors, the residue described as "dirty" in the observation was simply adventitious drug residue. The drug residue from the shift's compounding activity observed on the hot plate (thermaplate), the LAFW protective grill (HEPA filter), and the trash receptacles were immediately cleaned per SOP PHA-304. Of note, AIS's cleaning protocols, which include morning, mid-day, end of day, weekly, and monthly cleaning regimens, are robust in maintaining an aseptic processing environment that is compliant with USP <797>. Please see Ridgeland KPI #9, which states that AIS will inspect primary engineering controls (PECs) after compounding activities are completed and ensure each PEC is cleaned and disinfected appropriately. As previously noted, AIS has immediately translated the inspectors' observation to an institutionalized audit program (KPI #9) to ensure our aseptic processes are in strict compliance with USP <797>. Also, AIS immediately removed the storage bins containing compounding supplies that were located directly under the ISO Class 5 LAFW. While there is no USP <797> prohibition on storing compounding supplies in ISO Class 7 environments, AIS relocated these bins when pharmacy leadership noted an opportunity to optimize compounding workflow.

- **On 9/15/2015, a stock solution compounding pharmacist was observed improperly cleaning the LAFW prior to performing aseptic bulk compounding of fentanyl. The pharmacist sprayed 70% Sterile IPA directly on a sterile disposable cloth and wiped the workbench in a circular fashion, moving from front to back.**

AIS reviewed the organization's policy for cleaning and disinfecting of aseptic processing areas (PHA 304) and determined that it is in compliance with USP <797>. AIS re-educated all pharmacy staff on 09/17/15 regarding USP <797> compliant cleaning and disinfection processes for ISO Class 5 environments. Please see Ridgeland KPI #2. As previously noted, AIS has immediately translated the inspectors' observation to an institutionalized audit program (KPI #2) to ensure our aseptic processes are in strict compliance with USP <797>.

OBSERVATION 3

Separate or defined areas to prevent contamination or mix ups are deficient regarding operations related to aseptic processing of drug products.

AIS disagrees with this observation, including the premise that its practices are deficient to prevent contamination or mix-ups. The compounding workflow used by pharmacy personnel is necessitated by the reality that in pharmacy practice, patient-specific prescriptions issued by physicians often require aseptic combination of several medications. This observation, and the specific examples listed, address pharmacy practice issues that fall outside the scope of FDA's jurisdiction. AIS operates in compliance with pharmacy laws and regulations, as well as USP <797>. AIS has nevertheless reviewed each observation and has implemented improvements, as noted below, to further optimize compounding workflow.

Specifically,

- **Your firm's SOP, AIS-PHA-412: Conduct of Personnel in Controlled Areas and Aseptic Technique Overview, section 7.12 states Area Clearance: is an activity that ensures that only one "batch" is present at a compounding workstation to avoid error and mix-ups of the components and labels from which the CSP is being prepared.**

AIS has revised SOP PHA-412 in order to provide clarity regarding processes for our compounding personnel. Please note that AIS *does not batch produce end product*. The patient-specific prescriptions that AIS dispenses often require the aseptic combination of multiple medications.

- **On 9/15/2015, a pharmacist was observed pulling from 7 different stock medications in one ISO 5 hood.**

The patient-specific prescriptions that AIS dispenses often call for the aseptic combination of multiple medications. It is necessary for compounding personnel to have immediate access to multiple medications while fulfilling orders for patient-specific prescriptions.

- **On 9/15/2015, multiple unlabeled syringes from different stock solutions, for multiple patients, were observed lying on a cart waiting to be compounded.**

- **On 9/15/2015, multiple pharmacists were observed holding two separate prescriptions for two different patients, all syringes are unlabeled.**

Please note that AIS protocol dictates that patient-specific prescription labels travel with all patient-specific medication syringes as they rotate to different compounding stations in the cleanroom.

- **On 9/15/2015, powdered APIs were observed being weighed and staged, uncovered, in the ISO 7 area. The unlabeled, uncovered powder APIs were placed on a staging cart with multiple unlabeled syringes before being brought to the ISO 5 area.**

Please note that AIS protocol dictates that patient-specific prescription labels travel with all patient-specific medication syringes or powder APIs as they rotate to different compounding stations in the cleanroom.

- **On 9/15/2015, we observed multiple unlabeled compounded patient specific medications were placed in a hot water bath.**

Please note that AIS protocol dictates that patient-specific prescription labels travel with all patient-specific medication syringes or powder APIs as they rotate to different compounding stations in the cleanroom. AIS has augmented the labeling requirements for all patient-specific medications in a hot water bath.

AIS noted an opportunity to optimize compounding workflow by revising the protocol for transportation of patient-specific medications within the cleanroom. As noted above, AIS has

revised SOP PHA-412 in order to provide clarity regarding processes for our compounding personnel. Please see Ridgeland KPI #7. As previously noted, AIS has immediately translated the inspectors' observation to an institutionalized audit program (KPI #7) to ensure that compounding processes are unlikely to lead to the mix up of patient-specific CSPs.

OBSERVATION 4

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

- **Your firm's stock solutions undergo endotoxin testing one time prior to processing. However, your stock solutions are punctured multiple times during processing over several days. Your firm's stock solutions, at time of use, is not representative of the endotoxin testing conducted prior to processing.**

USP <797> mandates criteria for bacterial endotoxin (pyrogen) testing. Please note the *circumstances* that trigger the requirement for testing (numbered) as well as AIS's practice (*bulleted*):

All high risk levels CSPs, except for inhalation and ophthalmic administration, which are prepared in . . . .

1) groups of more than 25 identical single-dose packages (e.g., ampules, bags, syringes, vials)

    - Does not apply to AIS. As a pharmacy that only compounds unique medications for identified individual patients pursuant to a valid prescription issued by a licensed prescriber, AIS does not batch prepare end product.

2) in MDVs (multi-dose vials) for administration to multiple patients

    - Does not apply to AIS. AIS does not compound multi-dose vials, as this practice is incompatible with the patient population we serve.

3) that are exposed longer than 12 hours at 2 degrees C to 8 degrees C and longer than 6 hours at warmer than 8 degrees C before they are sterilized

    - Does not apply to AIS. AIS follows protocols to efficiently prepare each CSP. Even for the most complex CSPs, AIS completes all aseptic processing for each patient-specific CSP within 6 hours.

shall be tested to ensure that they do not contain excessive bacterial endotoxins . . . .

As mentioned above, AIS's compounding procedures do not trigger the USP <797> requirements for endotoxin testing. AIS nonetheless follows procedures and protocols that

minimize the introduction and generation of endotoxins during aseptic processing. AIS acquires its APIs from Medisca, a reputable, FDA-registered repackager. A Certificate of Analysis (COA) is provided and retained on file for each lot of API received by AIS, and one of the acceptance criteria listed on each COA is endotoxin levels. Also, AIS uses DynaLabs, an FDA-registered analytical lab, to test the endotoxin levels of each compounded stock solution, and the company ensures that endotoxin quantities are within acceptable limits before releasing the stock solution for use.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically,

- **On 9/15/2015, a pharmacist was observed crossing into the clean side of the anteroom with no shoe cover over their street shoes.**

AIS reviewed the organization's policy for garbing (PHA-404) and has determined that it is in compliance with USP <797>. AIS re-educated all pharmacy staff on 09/17/15 regarding the USP <797> compliant garbing procedures specified in PHA-404. Please see Ridgeland KPI #10. As previously noted, AIS has immediately translated the inspectors' observation to an institutionalized audit program (KPI #10) to ensure the garbing procedures of cleanroom personnel are in strict compliance with USP <797>.

- **On 9/15/2015, a pharmacist was observed reaching under the ISO 5 workbench to gather supplies to continue aseptic processing 24 times without sterilizing their gloves or the components entering ISO 5 area form a dirtier area.**

- **On 9/15/2015, a pharmacist compounding a stock solution of fentanyl was observed leaving the ISO 5 area, entering the ISO 7 area, and returning to the ISO 5 area 13 times before sanitizing their gloves.**

AIS reviewed the organization's policy that addresses the conduct of personnel in controlled environments (PHA-412) and had determined that it is in compliance with USP <797>. AIS re-educated all pharmacy staff on 09/17/15 regarding USP <797> compliant behavior for working in controlled environments specified in PHA-412. The training for pharmacy staff included instruction regarding how operators must interface with ISO Class 5 environments while engaged in aseptic processing. Please see Ridgeland KPIs #3 and #4. As previously noted, AIS has immediately translated the inspectors' observation to an institutionalized audit program (KPIs #3 and #4) to ensure that the conduct of all cleanroom personnel is in strict compliance with USP <797>.

- **On 9/15/2015, multiple pharmacists were observed with their heads under the ISO 5 hood.**

AIS reviewed the organization's policy that addresses the conduct of personnel in controlled environments (PHA-412) and has determined that it is in compliance with USP <797>. AIS re-educated all pharmacy staff on 09/17/15 regarding USP <797> compliant behavior for working in controlled environments specified in PHA-412. The training for pharmacy staff included instruction regarding how operators must interface with ISO Class 5 environments while engaged in aseptic processing. Please see Ridgeland KPI #1. As previously noted, AIS has immediately translated the inspectors' observation to an institutionalized audit program (KPI #1) to ensure that the conduct of all cleanroom personnel is in strict compliance with USP <797>.

* * *

In conclusion, AIS appreciates the opportunity to formally respond to each 483 observation. Evaluating and responding to each observation has reaffirmed for AIS that all of the pharmacy's processes, whether aseptic or procedural, are in place for the sole purpose of creating a sterile end product for our patients. AIS is proud that its pharmacy has never encountered a sterility failure with any of its CSPs.

ATTACHMENT B

CONFIDENTIAL

Via Overnight Mail

November 16, 2015

Ms. Ruth P. Dixon
District Director, New Orleans District
404 BNA Dr., Bldg. 200, Suite 500
Nashville, TN 37217-2597

Re: Response to Inspectional Observations – FEI Number 3011469631

Dear Ms. Dixon,

Please accept this correspondence in response to the FDA Form 483 provided to Advanced Infusion Solutions' ("AIS") facility in Clinton, Mississippi on October 27, 2015. As an organization, AIS is committed to complying with all applicable regulatory requirements. We appreciate the opportunity to respond to the inspectional observations contained in the 483. For ease of reference, the inspectional observations are repeated in bold text and our responses are set forth below each observation. Please note that the "Clinton" facility is a very small, local Jackson, Mississippi-area pharmacy that dispenses only patient-specific medications in a *low to medium risk* facility with an average daily census of approximately thirty (30) local patients.

While AIS believes its practices are in compliance with applicable regulatory requirements, including USP <797>, AIS views the FDA's 483 process as an opportunity for improvement. AIS has used this process to inquire, evaluate, bolster, and re-approach its entire quality assurance program, including but not limited to the ongoing engagement of a third-party consultant (CV attached as Exhibit 1) and the retention of a Director of Quality.

Since its inception, AIS leadership has been committed to improving performance by implementing pharmacy best practices and the USP <797> standards in sterile compounding. AIS recognizes the value of the USP <797> observations that FDA has brought to AIS's attention. Based on the FDA inspector's observations and USP <797> standards, corrective and preventive action (CAPA) plans and Key Performance Indicators (KPIs) were developed immediately to correct any observations, as well as to prevent recurrence of any future deviations from USP <797> standards. For AIS, quality improvement will continue with management monitoring the effectiveness of the KPIs using established audit tools.

The AIS leadership team has assigned managers as observers to conduct unannounced random audits in established frequencies to make sure that the compounding staff are strictly following USP <797> standards. All observations (sufficient or insufficient) are documented and

reviewed by the Pharmacist-in-Charge or a member of the senior leadership team. Any insufficient observations are addressed immediately and handled through remedial retraining/re-education. Any insufficient observations are re-evaluated and documented within 48 hours. All KPI-related findings are presented to AIS senior leadership to evaluate the effectiveness of the program.

For the AIS pharmacy location referenced above, based on the FDA inspectors' observations and the USP <797> standards, the leadership team has identified 16 KPI metrics in the areas of aseptic garbing, aseptic technique, cleanroom state of control, and the sterile product integrity. The KPI metrics began on 09/25/15. AIS will continue to audit and report these observations to the leadership team based on the established audit tool frequencies for each specific KPI (weekly, monthly, quarterly, and yearly). Please see the attached KPI dashboard from Clinton (attached as Exhibit 2).

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

- **On 1/15/2015, air and surface samples collected and analyzed by Hayes Microbial Consulting found multiple organisms of bacteria and fungus in your ISO 5 and ISO 8 areas. Your firm did not provide sufficient evidence indicating these areas are free of microbial contamination prior to your firm beginning operations at this facility on 2/9/2015.**

Based on USP <797> standards, AIS does not agree that its system for monitoring environmental conditions is deficient or poses any risk of harm to the public. Moreover, this observation fails to identify any applicable standard that AIS is alleged to have violated. AIS operates in strict compliance with USP <797>, and tests its systems, processes, and equipment regularly in accordance with USP <797> standards. Although our objective is no microbial growth in aseptic processing environments, AIS disagrees with the premise that an aseptic environment must at all times be free of microbial growth in order to safely produce CSPs.

The above observation does not reflect the full context and chronology of the facility's startup activities, as AIS did not begin dispensing low and medium risk CSPs until 02/09/15. After a period of inactivity, AIS relocated its home infusion operations to this facility. In anticipation of the relocation and for purposes of risk assessment, AIS requested that AirSafe, our vendor for controlled environment testing and certification, test and certify the cleanroom as a part of our validation efforts to recommission the facility for sterile compounding. Please note that this certification was performed in order to verify performance concerning the requirements set forth in USP <797>.

AIS requested that AirSafe ensure that the cleanroom complied with predetermined engineering specifications and operated in a sufficient a manner to provide and maintain a USP <797> compliant environment. Relevant measurements included air change rates, HEPA filter integrity,

room pressurization measurements, and non-viable particle counts. Regarding these measurements, AirSafe certified the cleanroom to be USP <797> compliant. AirSafe did recover microbial growth during its environmental sampling activities. In response to their findings, AIS performed a complete startup cleaning and disinfection of the cleanroom prior to commencing operations on 02/09/15. All startup cleaning was performed on 02/07/15 in accordance with our cleaning and disinfection policies and included the use of Peridox, a sporicidal disinfectant. Documentation of the startup cleaning, as well as subsequent cleaning activities, was provided to FDA inspectors. Of note, AIS's cleaning protocols at this facility, which include morning, end of day, and weekly cleaning regimens, are robust in maintaining an aseptic processing environment that is compliant with USP <797>.

Although the above observation does not reflect the full context and chronology of this facility's startup activities, AIS will nevertheless engage a third-party consultant to assist in developing a policy that defines AIS's procedures for startup and commissioning of cleanrooms. The policy will rely on industry best practices from relevant documents such as:

1. USP <797>; Pharmaceutical Compounding – Sterile Preparations
2. CETA CAG-003-2006-11; REV 31JAN12 – Certification Guide for Sterile Compounding Facilities
3. CETA CAG008-2010 REV 31JAN12 – Certification Matrix for Sterile Compounding Facilities
4. IEST-RP-CC006.3; Testing Cleanrooms (Institute of Environmental Sciences and Technology)
5. IEST-RPCC002.3; Unidirectional Flow Clean-Air Devices (Institute of Environmental Sciences and Technology)
6. IEST-RP-CC0034.3; HEPA and ULPA Filter Leak Tests (Institute of Environmental Sciences and Technology)
7. ISO 14644-1; Cleanrooms and Associated Controlled Environments – Part 1 – Classifications of Air Cleanliness
8. USP <1116>; Microbiological Evaluation of Cleanrooms and Other Controlled Environments

The policy will be completed in 90 days, and AIS will approve and add a policy to our library of SOPs. Please note, however, that AIS has no immediate future plans to recommission a facility.

- **Your firm's management states it performs surface and air monitoring in the ISO 5, ISO 7, and ISO 8 areas weekly. This is inadequate as environmental conditions are not performed each day sterile drug products are produced. In addition, the documentation provided by your firm indicates Bond Pharmacy did not start in-house environmental monitoring until on or about 7/30/2015, more than 5 months after your firm started production.**

Daily environmental monitoring is a cGMP requirement. USP <797> states: "Air sampling shall be performed at least semiannually (i.e., every 6 months) as part of the re-certification of facilities and equipment," and "Surface sampling shall be performed in all ISO classified areas on a periodic basis." In an effort to follow pharmacy best practices for *low and medium* risk

sterile compounding, AIS is currently performing both viable air and surface sampling on a monthly interval.

- **On 9/14/2015, gaps were observed around the perimeter of the pass through door from an unclassified area leading into the ISO 7 area.**

The FDA inspector made this observation on 09/14/15, and AIS provided evidence to FDA shortly thereafter that AIS remediated this finding by sealing these gaps around the perimeter of the pass through with cleanroom-appropriate caulk. AIS believes that the frequent cleaning of the pass through surfaces may have eroded the original caulking agent. Please see Clinton KPI #13. As previously noted, AIS has translated the inspectors' observation into an institutionalized audit program (KPI #13) to ensure that the cleanroom and compounding facilities are maintained in strict compliance with USP <797>.

- **According to your firm's SOP, AIS-PHA-408: "Gloved Fingertip Sampling", all new compounding personnel (compounding technicians, as well as, all pharmacist, regardless, of whether they physically perform the duties of compounding or they supervise compounding) must successfully complete 3 Gloved Fingertip sampling occurrences prior to compounding CSPs for human use. For low/medium risk level compounding, subsequent gloved fingertip sampling will occur annually.**

    - **Documentation provided by your firm indicates one pharmacy technician completed gloved fingertip sampling on 10/20/2015, 8 1/2 months after your firm became operational on 2/9/2015. Furthermore, on 9/14/2015, I observed 2 pharmacy technicians in your facility, only one pharmacy technician completed gloved fingertip sampling on 10/20/2015.**

All pharmacy compounding personnel are required to complete the sterile compounding training using Critical Point Sterile Compounding training program and 3 Gloved Fingertip sampling initially prior to actively compounding any patient specific sterile products, then annually for low to medium risk compounding per USP <797> standards. The observation (e.g., deviation from standard operating procedures) noted here resulted in immediate removal of the pharmacy technician from compounding any drugs until the technician completed gloved fingertip sampling on 10/20/2015. The Clinton pharmacy became operational on 02/09/15, but the new pharmacy technician did not start employment with AIS until 07/07/15. Please see Clinton KPIs #6 and #15. As previously noted, AIS has translated the inspectors' observation into an institutionalized audit program (KPIs #6 and #15) to ensure that the cleanroom and compounding facilities are maintained in strict compliance with USP <797>.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically,

- **Per your firm's SOP~ AIS-PHA-404: "Hand Hygiene and Garbing", section 4.3.5 describes hand washing will be performed for at least 30 seconds.**

    - **On 9/14/2015, a pharmacy technician was observed washing their hands in anteroom for approximately 10 seconds and drying their hands with a non-sterile disposable cloth.**

Sterile towels for hand hygiene is a cGMP requirement. In describing hand hygiene procedures, USP <797> states: "Hands and forearms to the elbows will be completely dried using either lint-free disposable towels or an electronic hand dryer." AIS reviewed the organization's policy for hand hygiene (PHA-404) and has determined that it is in compliance with USP <797>. AIS re-educated and trained all pharmacy staff on 09/17/15 regarding USP <797> compliant hand hygiene procedures specified in PHA-404. Please see Clinton KPI #16. As previously noted, AIS has translated the inspectors' observation into an institutionalized audit program (KPI #16) to ensure the hand hygiene procedures of cleanroom personnel are in strict compliance with USP <797>. To aid personnel with effective hand hygiene, AIS will add a clock to its anteroom to facilitate compliance with PHA-404.

- **According to your firm's SOP, AIS-PHA-404: "Hand Hygiene and Garbing", section 4.4.9, gloved hands will be sprayed with sterile 70% IPA prior to entering the ISO 5 area and anytime the employee's hand re-enters the ISO 5 area.**

    - **On 9/14/2015, a pharmacy technician was observed placing the outer covering of a 0.9% NaC11000-mL bag into the trash receptacle in the ISO 7 area and returning to the ISO 5 area without sanitizing their gloves.**

AIS reviewed the organization's policy for hand hygiene (PHA-404) and has determined that it is in compliance with USP <797>. AIS has re-educated and trained all pharmacy staff on 09/17/15 regarding USP <797> compliant hand hygiene procedures specified in PHA-404. Please see Clinton KPI #4. As previously noted, AIS has immediately translated the inspectors' observation to an institutionalized audit program (KPI #4) to ensure the hand hygiene procedures of cleanroom personnel are in strict compliance with USP <797>.

OBSERVATION 3

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

- **Per your firm's SOP, AIS-PHA-404: "Hand Hygiene and Garbing", section 4.3.8 states to don a clean, lint free cover garment (Tyvek or equivalent) with sleeves that fit snugly around the wrists and which securely encloses the neck. In addition, section 4.3.10 of the aforementioned SOP, states to fasten the closures of the gown completely.**

    - **On 9/14/2015, a pharmacy technician was observed wearing a non-sterile gown that was open, exposing their street clothes to the sterile environment.**

AIS reviewed the organization's policy for garbing (PHA-404) and has determined that it is in compliance with USP <797>. AIS immediately re-educated and trained all pharmacy staff on 09/17/15 regarding USP <797> compliant garbing procedures specified in PHA-404. Please see Clinton KPI #14. As previously noted, AIS has translated the inspectors' observation into an institutionalized audit program (KPI #14) to ensure the garbing procedures of cleanroom personnel are in strict compliance with USP <797>.

- **Per your firm's SOP, AIS-PHA-404: "Hand Hygiene and Garbing", section 4.5.1.3, gowns may be saved for subsequent use during the same shift/day and must be hung on a hook on the clean side of the anteroom.**
    - **On 9/14/2015, a pharmacy technician was observed dragging their gown on the floor of the anteroom from the clean side to the dirty side and then hung up the gown on the dirty side of the anteroom to be reused.**
    - **On 9/14/2015, another pharmacy technician was observed entering the anteroom from the buffer room, and then hung their gown on the dirty side of the anteroom for subsequent use.**

AIS reviewed the organization's policy for garbing (PHA-404) and has determined that it is in compliance with USP <797>. AIS immediately re-educated and trained all pharmacy staff on 09/17/15 regarding USP <797> compliant garbing procedures specified in PHA-404. Please see Clinton KPI #14. As previously noted, AIS has translated the inspectors' observation into an institutionalized audit program (KPI #14) to ensure the garbing procedures of cleanroom personnel are in strict compliance with USP <797>.

- **The gowning components your firm uses during aseptic processing are not sterile. The gowns, hair covers, face masks, and shoe covers are stored in an unclassified area. Furthermore, the gowns are stored in an open bag.**
    - **On 9/14/2015, a pharmacy technician was observed without a beard net and no eye protection while processing in the ISO 7 and ISO 5 areas.**

Sterile garb is a cGMP requirement. AIS reviewed the organization's policy for garbing (PHA-404) and has determined that it is in compliance with USP <797>, which requires cleanroom personnel to don non-sterile shoe covers, a non-sterile hair net, a non-sterile facemask, and a non-sterile gown. Eye protection is not required by USP <797>, nor is it mandated by AIS policy as the pharmacy does not dispense hazardous drugs.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

- **In the ISO 7 area (Buffer Room), rust spots were observed on floor, and what appears to be residue streaks were observed on the walls. Your ISO 7 area is adjacent to your**

firm's ISO 5 area, where production occurs. Furthermore, no physical barrier distinguishes your firm's ISO 7 area from the ISO 5 area.

As discussed with FDA inspectors, the residue described as "rust spots" on the floor in the observation was adventitious residue from a stainless steel cart wheel. AIS cleaned the areas noted by the inspectors, per protocol, on the same day that the observation was made. A new cleanroom floor that is smooth, seamless, impervious, and easily cleanable was installed in this cleanroom in January 2015, prior to commencing operations. Also the finding described as "residue streaks" is a cosmetic imperfection in the plastic wall of the ISO Class 7 buffer room. AIS confirmed with FDA inspectors while onsite that the area on the wall is smooth, impervious, and easily cleanable.

A physical barrier between the ISO Class 5 and ISO Class 7 areas is not a USP <797> requirement. AIS has conducted smoke studies, a USP <797> requirement, of the cleanroom's primary and secondary engineering controls. These studies demonstrate that the vertical laminar flow bench is providing unidirectional air flow throughout the direct compounding area.

- **According to the SOP, AIS-PHA-304: "Cleaning and Disinfecting of the Compounding Facility", cleaning will be performed in the ISO 5 area (VLAFW) prior to the beginning of each shift, immediately prior to each batch, every 30 minutes throughout the shift when ongoing drug production activities are occurring, after spills, and when microbial contaminations known to have been or is suspected of having been introduced.**

  - **Your firm provided a sample of the cleaning log for 9/14/2015 and a sample log from 7/10-16/2015 which shows daily cleaning only occurs at the beginning and end of the day.**

AIS has revised and clarified PHA-304 to require only documentation of beginning and end-of-the-day cleaning activities. USP <797> does not require the documentation of cleaning activities that are performed throughout a prolonged period of aseptic processing. AIS is concerned that requiring strict documentation of all in-process cleaning and disinfecting activity would force compounding personnel to exit ISO Class 5 environments during aseptic processing. Pharmacy leadership believes this is an unnecessary intervention.

* * *

In conclusion, AIS appreciates the opportunity to formally respond to each 483 observation. Evaluating and responding to each observation has reaffirmed for AIS that all of the pharmacy's processes, whether aseptic or procedural, are in place for the sole purpose of creating a sterile end product for our patients. AIS is proud that its pharmacy has never encountered a sterility failure with any of its CSPs.

Bond Pharmacy, Inc. dba Advanced Infusion Solutions 3/1/17

New Orleans District
404 BNA Drive
Building 200 - Suite 500
Nashville, TN 37217
Telephone: (615) 366-7801
FAX: (615) 366-7802

March 1, 2017

Warning Letter No. 2017-NOL-06

UNITED PARCEL SERVICE
Delivery Signature Requested

Charles R. Bell, President and COO
Bond Pharmacy, Inc.
dba Advanced Infusion Solutions
623 Highland Colony Parkway, Suite 100
Ridgeland, Mississippi 39157-6077

Dear Mr. Bell:

From September 15 to October 27, 2015, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, Bond Pharmacy, Inc., dba Advanced Infusion Solutions, located at 623 Highland Colony Parkway, Suite 100, Ridgeland, Mississippi. This inspection was conducted after receipt of an FDA MedWatch report concerning baclofen 500mcg/mL, bupivacaine 5mg/mL, and hydromorphone25 mg/mL injection, prepared by your firm, that was used to refill an intrathecal pain pump. During the inspection, the FDA investigators observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483, Investigational Observation (Form FDA 483) to your firm on October 27, 2015. FDA acknowledges receipt of your firm's response to the Form FDA 483 dated November 16, 2015. Based on this

inspection, it appears you are producing drugs that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Violations of the FDCA

Adulterated Drug Products

The FDA investigators noted that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have been contaminated with filth, or rendered injurious to health, causing your products to be adulterated under Section 501(a)(2)(A) of the FDCA [21 United States Code (USC) 351(a)(2)(A)]. For example, the FDA investigators observed poor aseptic practices, including an operator not disinfecting or changing their gloves prior to introducing them into the ISO 5 area from the ISO 7 area and after touching non-sterile material. Multiple operators with non-sterile gowning and exposed facial skin were observed leaning into the ISO 5 work area. Investigators noted that your firm exposed stock solutions, intended to be sterile, to lower than ISO 5 quality air. Specifically, they observed the storage of said solutions in an unclassified area for further use after the container closure system had been punctured multiple times, and therefore compromised, throughout the assigned expiry period. Investigators collected a sample of unused wipes, intended for use in disinfecting the aseptic processing areas, from within your cleanroom for testing. Testing results of the sample identified microbial contamination, including spore-forming bacteria.

It is a prohibited Act under Section 301(k) of the FDCA to do any Act with respect to a drug, if such Act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

B. Corrective Actions

We have reviewed your firm's response to the Form FDA 483. Although several of your proposed corrective actions appear adequate, others are deficient. For example, in your response to our observation regarding stock solutions that are punctured multiple times during processing over several days and are stored in an unclassified area, you stated that your compounding procedures do not trigger the USP <797> requirements for endotoxin testing. You also stated your firm follows procedures and protocols that minimize the introduction and generation of endotoxin during aseptic processing and perform endotoxin testing of each stock solution before releasing the stock solution for use. However, your response did not address the practice of storing stock solutions, intended to be sterile, for further use in unclassified air with a compromised container-closure throughout the expiry period.

FDA strongly recommends that your management immediately undertake a comprehensive assessment of your operations, including facility design, procedures, personnel, processes, materials, and systems. In particular, this review should assess your aseptic processing operations. A third party consultant with relevant sterile drug processing expertise could be useful in conducting this comprehensive evaluation.

C. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within 15 working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Please include an explanation of each step being taken to prevent the recurrence of

violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If the corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your written notification should be addressed to:

Mark Rivero, Compliance Officer
U.S. Food and Drug Administration
New Orleans District
404 BNA Drive
Building 200, Suite 500
Nashville, TN 37217-2597

If you have questions regarding any issues in this letter, please contact Mark Rivero, Compliance Officer via email at Mark.Rivero@fda.hhs.gov or by phone at (504) 846-6103. (mailto:Mark.Rivero@fda.hhs.gov)

Sincerely,
/S/
Ruth P. Dixon
District Director
New Orleans District

cc: Sheldon Bradshaw, Partner
Hutton & William, LLP
2200 Pennsylvania Avenue, NW
Washington, DC 20037- 1701

Response Letter

- Bond Pharmacy, Inc. dba Advanced Infusion Solutions - Response Letter 3/23/17 (/ICECI/EnforcementActions/WarningLetters/2017/ucm548578.htm)
- Bond Pharmacy, Inc. dba Advanced Infusion Solutions - Response Letter 8/10/17 (/ICECI/EnforcementActions/WarningLetters/2017/ucm573003.htm)

More in 2017 (/ICECI/EnforcementActions/WarningLetters/2017/default.htm)

Bond Pharmacy, Inc. dba Advanced Infusion Solutions - Response Letter 3/23/17

DUANE MORRIS LLP
190 SOUTH LASALLE STREET, SUITE 3700
CHICAGO, IL 60603-3433
PHONE: +1 312 499 6700
FAX:+1 312 499 6701

FIRM and AFFILIATE OFFICES

RACHAEL G. PONTIKES
DIRECT DIAL: +1 312 499 6757
PERSONAL FAX: +1 312 277 6903
E-MAIL: RGPontikes@duanemorris.com
www.duanemorris.com

Mark Rivero, Compliance Officer
U.S. Food & Drug Administration
New Orleans District
404 BNA Drive
Building 200, Suite 500
Nashville, TN 37217-2597
Mark.Rivero@fda.hhs.gov (mailto:Mark.Rivero@fda.hhs.gov)

Re: Bond Pharmacy, Inc. d/b/a Advanced Infusion Solutions' Response to Warning Letter --Ref#: 2017-NOL-06

Dear Mr. Rivero:

We represent Bond Pharmacy, Inc. d/b/a Advanced Infusion Solutions ("AIS"), and hereby submit to the U.S. Food & Drug Administration ("FDA") this letter in response to FDA's Warning Letter dated March 1, 2017 (the "Warning Letter") to AIS. Please note that AIS received the Warning Letter on March 2, 2017.

AIS wishes to emphasize that it takes the issues identified in the Warning Letter very seriously. AIS is a compounding pharmacy acting in full compliance with all relevant state laws governing the practice of pharmacy. There is no dispute that AIS complies with Section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA"), as it compounds exclusively pursuant to a patient specific prescription. As such, AIS is governed by state law and it is

the state boards of pharmacy-not FDA-that act as AIS's primary regulator. Moreover, as a pharmacy compliant with Section 503A, AIS is exempt from certain requirements under the FDCA reserved for drug manufacturer, like FDA's current good manufacturing practices ("cGMP").

Therefore, contrary to FDA's suggestion, AIS is ***not*** "producing drugs that violate the [FDCA]." As the Warning Letter does not identity any federal law of which AIS is in violation, AIS requests that this statement be retracted.

Furthermore, according to FDA's published policy on warning letters, "the agency position is that Warning Letters are issued only for violations of regulatory significance."***1*** The issuance of the Warning Letter to AIS is entirely inappropriate for the following reasons: (1) the Warning Letter applies regulatory standards that do not apply to AIS as a compounding pharmacy in full compliance with Section 503A; (2) even if these standards did apply to AIS (they do not), AIS addressed all of FDA's concerns as demonstrated in its November 16, 2015 response to FDA's Form 483 and as further demonstrated below; and (3) simply put, none of the observations set forth in the Warning Letter rise to the level of "regulatory significance" required under FDA's stated policy. AIS respectfully requests, therefore, that FDA withdraw its Warning Letter.

I. AIS Is a Section 503A-Compliant Pharmacy Subject to State Law-FDA Should Not Apply cGMP Or Any Other Standard To AIS.

AIS is a pharmacy that provides unique specialized medication for identified individual patients pursuant to a valid prescription issued by a licensed prescriber. Thus, pursuant to Section 503A, AIS is primarily regulated by state law which incorporates United States Pharmacopeia ("USP") Chapter 797 governing sterile preparations. As it is, the states interpret and enforce their own laws, and FDA's Form 483 observations, as well as its Warning Letter, do not (nor could they) identify any state law, state regulation, or USP <797> standard of which AIS is in violation. Under Section 503A, AIS is also exempt from, among other things, cGMP requirements. Nevertheless, FDA appears to apply cGMP standards or something other than the standards set out in USP <797> to AIS. For example, FDA continues to claim that AIS is required to use sterile wipes, although USP <797> does not require the use of sterile wipes in the cleanroom suite. Likewise, FDA appears to claim that AIS is required to use sterile gowning and to avoid exposed facial skin in the ISO 5 work area, although USP <797> does not require such practices. FDA appears to be suggesting that AIS is compounding "under insanitary conditions" because it is not compounding in conformity with cGMP. Yet, FDA's application of cGMP or any other standard to AIS is utterly improper.

Furthermore, the Warning Letter appears to improperly hold AIS to standards outside applicable state and federal law to determine if its compounds are prepared under insanitary conditions and are therefore adulterated under Section 501(a)(2)(A) of the FDCA. For example, the Warning Letter cites that FDA observed "the storage of [stock] solutions in an unclassified area for further use after the container closure system had been punctured multiple times, and therefore compromised, throughout the assigned expiry period." The Warning letter seems to rely on this observation as an example of FDA's suggestion that AIS may be compounding drugs under insanitary conditions. However, the stock solution practices that FDA observed cannot form the basis for any suggestion that AIS may be compounding under insanitary conditions, as these practices are compliant with the general principles outlined in USP <797>. FDA cites no applicable state or federal law or regulation under which FDA's observation of AIS's treatment of stock solutions is improper.

II. AIS Has Addressed All Issues Raised By FDA.

Notwithstanding AIS's objections to the Warning Letter, it should be noted that following receipt of FDA's Form 483 more than seventeen months ago, AIS undertook a comprehensive review and evaluation of FDA's observations, as well as AIS's compounding operations, and took a variety of actions. AIS communicated this information to FDA in its November 16, 2015 response to the Form 483. Please note that AIS's cooperation with FDA should not be interpreted as a waiver of any of the above objections.

Specifically, in response to the Form 483, AIS addressed the following:

• **Operator Transition from ISO 7 to ISO 5 Area**: FDA notes that its investigators observed "an operator not disinfecting or changing their gloves prior to introducing them into the ISO 5 area from the ISO 7 area and after touching non-sterile material." AIS responded to this observation at page 11 of its response to FDA's Form 483, wherein it stated that AIS reviewed its procedures and determined that its procedures were in full compliance with USP <797> standards for pharmacy staff working in controlled environments. See Exhibit 1, Attachment A at 11. Despite this determination, AIS conducted re-education training on USP <797> standards for all of its staff and translated FDA's observations into key performance indicators ("KPI") to ensure that the conduct of all cleanroom personnel remained in strict compliance with USP <797> standards. *Id.*

• **Garbing Procedure**: FDA notes that its investigators observed "multiple operators with non-sterile gowning and exposed facial skin were observed leaning into the ISO 5 work area." With respect to non-sterile gowning and exposed facial skin, FDA does not list any such observation in its Form 483; therefore, this is the first instance where AIS has been made aware of such an observation. Please note that USP <797> does not prohibit the use of non-sterile gowning and exposed facial skin in the ISO 5 work environment. AIS has reviewed its policies and procedures, and can verify that AIS only uses sterile gowning (to be clear, AIS continues to and was using only sterile gowning at the time of the inspection) and that it monitors and immediately remediates any deviation from sterile compounding best practices and USP <797> standards related to exposed facial skin.

With respect to FDA's observation that "operators ... were observed leaning into the ISO 5 work area," AIS responded to this observation at page 12 of its response to FDA's Form 483, stating that AIS reviewed its policies addressing the conduct of personnel in controlled environments (PHA-412) and determined that it was in compliance with USP <797> standards. See Exhibit 1, Attachment A at 12. Nevertheless, AIS conducted re-education training on USP <797> standards and sterile compounding best practices for all of its staff, and translated FDA's observations to a KPI in order to ensure that the conduct of all cleanroom personnel remained in strict compliance with USP <797>.

• **Stock Solutions**: FDA notes that its investigators observed that AIS "exposed stock solutions, intended to be sterile, to lower than ISO 5 quality air." Specifically, FDA observed "the storage of stock solutions in an unclassified area for further use after the container closure system has been punctured several times, and therefore compromised, throughout the expiry period."

In response to FDA's Form 483 observations, AIS reevaluated its procedures related to stock solutions, and elected to treat all stock solution containers as a single dose vial in accordance with USP <797> standards for single dose vials. To that end, AIS has modified its procedures in the following three ways:

(1) All stock solutions are packaged in multiple containers, with each container treated as a single-dose vial. Each stock solution container is accessed via a needle-free access device. See Exhibit 2, identifying the needle-free access device currently used by AIS. Each container is punctured only once, and the needle-free connector maintains the integrity of the container and acts as a barrier to bacterial ingress;

(2) After the initial access of the stock solution container via a needle-free connector, the stock solution is maintained exclusively in an ISO 5 environment and is disposed of after a period of no more than six hours; and

(3) Due to the additional steps identified above, and to ensure that each step is strictly followed, AIS has dedicated a pharmacist specifically to manage the storage, use, and integrity of stock solutions.

The above procedures ensure that no stock solutions are punctured and used in compounding in unclassified areas.

• **Wipes**: FDA notes that its investigators "collected a sample of unused wipes" and that testing results "identified microbial contamination, including spore-forming bacteria." As AIS stated in its email to you dated December 10, 2015, USP <797> does not require the use of sterile wipes to handle non-sterile API. Nevertheless, in response to FDA's Form 483, and as a best practice, AIS now only uses sterile wipes in the ISO 5 environment.

III. Conclusion

In closing, AIS would like to emphasize that it takes compliance with all applicable state and federal laws governing its pharmacy practice and the Warning Letter very seriously. AIS shares FDA's goal of ensuring that patients in need of custom compounded medications receive the highest quality preparations. The Warning Letter does not identify any federal law of which AIS is in violation and appears to apply regulatory standards that do not apply to AIS as a compounding pharmacy in full compliance with Section 503A. Since FDA's inspection and its Form 483 issued in October 2015, AIS has identified, addressed, and corrected all of FDA's concerns raised in its Form 483 and Warning Letter.

As none ofthe observations set forth in the Warning Letter rise to the level of"regulatory significance" required under FDA's stated policy, we respectfully request that the Warning Letter be withdrawn and a closeout letter be issued without delay.

Very truly yours,

/S/

Rachael G. Pontikes

---

1 4-1-1- Warning Letter Procedures, FDA Regulatory Procedures Manual, https://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf (https://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UC).

March 23, 2017

VIA EMAIL AND EXPRESS MAIL

More in 2017 (/ICECI/EnforcementActions/WarningLetters/2017/default.htm)

U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

July 14, 2017

Charles R. Bell, President and COO
Bond Pharmacy, Inc.
dba Advanced Infusion Solutions
623 Highland Colony Parkway, Suite 100
Ridgeland, Mississippi 39157-6077

RE: Bond Pharmacy, Inc. dba Advanced Infusion Solutions
Warning Letter (Ref # 2017-NOL-06)

Dear Mr. Bell:

This letter acknowledges receipt of a Warning Letter response letter dated March 23, 2017, in which Ms. Rachel Pontikes responded to FDA's warning letter (ref: WL# 2017-NOL-06) dated March 1, 2017, on your firm's behalf.

FDA acknowledges the statements that AIS "takes the issues identified in the [w]arning [l]etter very seriously" and "shares FDA's goal of ensuring that patients in need of custom compounded medications receive the highest quality preparations." We also note that, in the response to the warning letter, it was stated that the issuance of the warning letter was "inappropriate" because:

> "(1) the [w]arning [l]etter applies regulatory standards that do not apply to AIS as a compounding pharmacy in full compliance with 503A; (2) even if these standards did apply to AIS (they do not), AIS addressed all of FDA's concerns as demonstrated in its November 16, 2015 response to FDA's Form 483 ... ; and (3) ... none of the observations set forth in the [w]arning [l]etter rise to the level of 'regulatory significance' required under FDA's stated policy."

As a result, it was requested that FDA withdraw the warning letter. For the following reasons, we decline to do so:

(1) Section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies to the firm regardless of whether drug products compounded by the firm meet the conditions of section 503A. As our warning letter stated, the conditions observed during our inspection and described in the warning letter are violations of section 501(a)(2)(A).

(2) As our warning letter stated in the corrective actions section, the firm's November 16, 2015, response to the Form FDA 483 did not adequately

address all of the observed insanitary conditions.

(3) The insanitary conditions described in the warning letter, if not corrected, could lead to the contamination of products intended to be sterile; we consider the insanitary conditions to be of regulatory significance.

Regarding the insanitary conditions noted in the warning letter, some of the proposed corrective actions appear to be adequate. However, we are unable to fully evaluate the following corrective actions due to a lack of supporting documentation:

(1) In the response, it was stated that "All stock solutions are packaged in multiple containers, with each container treated as a single-dose vial. Each stock solution container is accessed via a needle-free access device." In addition, it was stated that "Each container is punctured only once, and the needle-free connector maintains the integrity of the container and acts as a barrier to bacterial ingress." From the information provided in the response, it appears that this technology is designed for use with peripheral, arterial, and central venous catheters. Because of the lack of information regarding the ability of this plan to prevent contamination of stock solutions, we did not have adequate information for review regarding the needle-free connector's ability to maintain the integrity of the container and to act as a barrier to bacterial ingress.

(2) We acknowledge the statement that "AIS now only uses sterile wipes in the ISO 5 environment." However, because no supporting documentation, such as invoices, a product label, or an updated procedure, was provided for our review, we could not fully evaluate the proposed corrective action.

During our next inspection of your facility, we will verify that you no longer prepare, pack, or hold drug products under insanitary conditions. Failure to implement adequate corrections may result in legal action without further notice, including, without limitation, seizure and injunction.

As requested, we will post your March 23, 2017, response to the warning letter on our website. We also intend to post this letter. If you have any questions, please contact Mark Rivero, Compliance Officer, at (504) 846-6103.

Sincerely,

/Monica R. Maxwell/

Digitally signed by Monica R. Maxwell -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300060034, cn=Monica R. Maxwell -S
Date: 2017.07.13 14:56:51 -05'00'

Monica R. Maxwell
Acting Program Division Director
Office of Pharmaceutical Quality Operations, Division 2

John W. Diehl -S

Digitally signed by John W. Diehl -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S, 0.9.2342.19200300.100.1.1=2000099727
Date: 2017.07.13 13:16:17 -05'00'

Reviewed by: _____ Date: _____

CLEARANCE

bcc: HFC-230, Office of Compliance Policy
HFI-35 via CMS unpurged (Melissa Williams)
HFC-134 DEIO/ORA
HFD-317 CDER Compounding Team
Legal File
ADIB/CRG/JPP/MDJ/DAT/GCP/LTM via email
EI File (FEI 3011804748)
NOL-DCTM, CB

MWR

CMS 497408

Firm's phone number: (769) 300-0740

Supplemental #2
June 15, 2018
11:27 A.M.

Bond Pharmacy, Inc. dba Advanced Infusion Solutions - Response Letter 8/10/17

AIS Leading the Way in Intrathecal PainCare

August 10, 2017

VIA EXPRESS MAIL

Monica R. Maxwell
Acting Program Division Director
U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations,
Division 2
4040 N. Central Expressway, Suite 300
Dallas, TX 75204

Re: Bond Pharmacy, Inc. d/b/a Advanced Infusion Solutions ("AIS") Warning Letter (Ref# 2017-NOL-06)

Dear Ms. Maxwell:

I write in response to your letter dated July 14, 2017, wherein you identified additional information that you needed to evaluate AIS's proposed corrective actions in its response to the U.S. Food & Drug Administration's ("FDA") March 1, 2017 Warning Letter ("A/S's FDA Response"). I understand FDA's interest in ensuring that AIS, like all other Section 503A compounding pharmacies, provides its patients with safe compounded medication. I wish to assure FDA that AIS has this same interest, and that it will take any and all steps necessary to cooperate with FDA as it continues its review. To that end, I hope the following additional information assists you in evaluating AIS's corrective actions.

First, AIS appreciates the need to prevent any alleged or potential contamination of its stock solutions through exposure to lower than ISO class 5 quality air. As stated in AIS's FDA Response, "AIS reevaluated its procedures related to stock solutions" and, among the steps mentioned, "elected to treat all stock solution containers as a single dose vial" and to access each vial using a "needle-free access device." AIS believes its use of the needle-free access device will prevent contamination of its stock solutions because its use is an integral part of AIS's overall revised procedure for accessing stock solutions.

AIS's revised procedure takes place entirely in an ISO class 5 environment, using only sterile equipment. First, the stock solution bag is cleaned and disinfected using appropriate aseptic technique and placed in an ISO class 5 environment. Once inside the ISO class 5 environment, the stock solution is accessed using the sterile, needle-free

access device. The accessed stock solution remains in the ISO class 5 environment at all times. In preparing patient-specific compounded sterile products, withdrawal of the contents of the stock solution is done aseptically using only sterile syringes. AIS's policy, moreover, is to discard the stock solution container after six hours of use regardless of whether all of the contents of the stock solution have been used. A photographic representation of AIS's procedure is attached hereto, along with a data sheet on the device, photographs of the device packaging reflecting proof of sterility, and a brochure explaining the device's use in preparing sterile preparations. See Group Exhibit A. In sum, although it is true that the needle-free access device was first developed for catheters, the same technology is now available for compounders and is a vital component of AIS 's overall procedure to ensure that its stock solutions remain free of any potential contamination.

Second, with respect to AIS's stated use of sterile wipes, the supporting documentation you requested is attached hereto. The documentation includes Certificates of Conformance, Analysis and Sterility for the sterile wipes, see Exhibit B, and 70% sterile IPA, see Exhibit C, that AIS has purchased from Contee® over the last seven months. In addition, I have attached invoices for the sterile wipes and 70% sterile IPA dating back to June 2016, see Exhibit D, and a photograph of the sterile wipes AIS uses from Contee®, see Exhibit E. AIS has, moreover, updated its policy, PHA-412- RDG-Conduct of Personnel in Controlled Areas and Aseptic Technique Overview, to reflect the following:

> 8.2: All work areas are to be cleaned and disinfected according to PHA-304. Specifically only sterile wipes will be used in an ISO Class 5
> environment.

This supporting documentation and policy revisions affirm AIS's statement made in its FDA Response that it "now only uses sterile wipes in the ISO 5 environment."

Please do not hesitate to reach out to me should you have any additional questions or concerns.

Very truly yours,
/s/
Charles (Chuck) R. Bell, Jr., PharmD, RPh

623 Highland Colony Parkway, Suite 1 00
Ridgeland, MS 39157
p 601.988.1700 877 443.4006
F: 601.988.1701 888.298.2220
info@aispaincore com
www.aispaincore.com

More in 2017 (/ICECI/EnforcementActions/WarningLetters/2017/default.htm)

Clinton, MS location
Supplemental #2
June 15, 2018
11:27 A.M.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District
404 BNA Drive
Building 200, Suite 500
Nashville, TN 37217

Phone: 615-366-7801
Fax: 615-366-7802

August 2, 2016

Frank Gammill
Executive Director
Mississippi Board of Pharmacy
6360 I-55N, Suite 400
Jackson, MS 39211

Dear Mr. Gammill:

The purpose of this letter is to refer the Mississippi State Board of Pharmacy (BOP) for appropriate follow-up, of the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Mississippi BOP, Bond Pharmacy dba Advanced Infusion Solutions, located at 132 Fairmont Street, Suite B, Clinton, MS 39056 (Pharmacy Permit #14064, exp. December 31, 2017).[1]

FDA inspected the firm from September 14, 2015, to October 27, 2015. FDA investigators were accompanied by Mississippi state investigators for one day. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm472930.pdf

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Advanced Infusion Solutions, and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and dispenses.

During the inspection, the FDA investigators observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. For example, our investigators observed an operator leaving the ISO 5 area and then returning to proceed with aseptic manipulations without sanitizing or changing their gloves. Furthermore, our investigators observed discoloration from a stainless steel cart wheel on the floor in the ISO 7.

[1] Advanced Infusion Solutions also operates a facility located at 623 Highland Colony Parkway, Suite 100, Ridgeland, MS 38157. This letter does not address the Ridgeland, MS facility.

Advanced Infusion Solutions committed to correcting the deviations in its response to the Form FDA 483, dated November 16, 2015.[2] In addition, the deviations identified appear to be readily correctable.

After review of the record, at this time FDA does not intend to take further action with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients, consistent with traditional pharmacy practice, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Mississippi State BOP for follow-up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Mark Rivero, Compliance Officer, at (504) 846-6103 or by email at Mark.Rivero@fda.hhs.gov.

Sincerely,

Ruth P. Dixon
District Director
U.S. Food and Drug Administration
New Orleans District Office

MWR/mag

[2] Because you are an FDA commissioned official, you can request an un-redacted copy of the Form FDA 483 or the firm's response to the Form FDA 483.

Supplemental Response:

28. Project Completion Chart

Supplemental Attachment 26

Revised Project Completion Forecast Chart

PROJECT COMPLETION FORECAST CHART

Assuming the Certificate of Need (CON) approval becomes the final HSDA action on the date listed in Item 1. below, indicate the number of days from the HSDA decision date to each phase of the completion forecast.

Phase	Days Required	Anticipated Date [Month/Year]
1. Initial HSDA decision date		August 22, 2018
2. Architectural and engineering contract signed		
3. Construction documents approved by the Tennessee Department of Health		
4. Construction contract signed		
5. Building permit secured		
6. Site preparation completed		
7. Building construction commenced		
8. Construction 40% complete		
9. Construction 80% complete		
10. Construction 100% complete (approved for occupancy		
11. *Issuance of License		December 22, 2018
12. *Issuance of Service		June 22, 2019
13. Final Architectural Certification of Payment		
14. Final Project Report Form submitted (Form HR0055)		

***For projects that *DO NOT* involve construction or renovation, complete items 11 & 12 only.**

NOTE: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date

Supplemental #2
June 15, 2018
11:27 A.M.

Supplemental Response:

29. Proof of Publication

Supplemental Attachment 27

Publication of Intent Chart

Proof of Newspaper Publications

NEWSPAPER NAME	DATE OF PUBLICATION	COUNTIES SERVED
Alamo - The Crockett County Times	4/4/2018	CROCKETT
Athens - The Daily Post-Athenian	4/6/2018	MCMINN, Meigs
Bolivar - Bulletin-Times	4/5/2018	HARDEMAN
Brownsville - Brownsville States Graphic	4/4/2018	HAYWOOD
Byrdstown - Pickett County Press	4/5/2018	PICKETT
Camden - The Camden Chronicle	4/5/2018	BENTON
Carthage - Carthage Courier	4/5/2018	SMITH
Celina - Citizen-Statesman	4/3/2018	CLAY
Centerville - Hickman County Times	4/9/2018	HICKMAN
Chattanooga - Chattanooga Times Free Press	4/6/2018	HAMILTON, Marion, Sequatchie, Bledsoe, Rhea, Bradley and Polk
Columbia - The Daily Herald	4/6/2018	MAURY
Cookeville - Herald-Citizen	4/6/2018	PUTNAM
Crossville - Crossville Chronicle	4/6/2018	CUMBERLAND
Dyersburg - State Gazette	4/6/2018	DYER
Elizabethton - Elizabethton Star	4/6/2018	CARTER
Erwin - The Erwin Record	4/4/2018	UNICOI
Fayetteville - The Elk Valley Times	4/4/2018	LINCOLN
Gainesboro - Jackson County Sentinel	4/3/2018	JACKSON
Greeneville - Greeneville Sun	4/6/2018	GREENE
Hartsville - The Hartsville Vidette	4/5/2018	TROUSDALE
Henderson - Chester County Independent	4/5/2018	CHESTER
Hohenwald - Lewis County Herald	4/5/2018	LEWIS
Huntingdon - Carroll County News-Leader	4/4/2018	CARROLL
Jackson - The Jackson Sun	4/6/2018	MADISON
Jamestown - Fentress Courier	4/4/2018	FENTRESS
Johnson City - Johnson City Press	4/6/2018	WASHINGTON
Kingsport - Kingsport Times-News	4/6/2018	SULLIVAN
Kingston - Roane County News	4/6/2018	ROANE
Knoxville - Knoxville News-Sentinel	4/6/2018	KNOX, Anderson, Union, Grainger, Jefferson, Sevier, Blount, and Loudon
Lafayette - Macon County Times	4/5/2018	MACON
LaFollette - LaFollette Press	4/5/2018	CAMPBELL
Lawrenceburg - The Democrat Union	4/6/2018	LAWRENCE
Lewisburg- Marshall County Tribune	4/6/2018	MARSHALL
Lexington - Lexington Progress	4/4/2018	HENDERSON
Linden - Buffalo River Review	4/4/2018	PERRY
Livingston - Overton County News	4/3/2018	OVERTON
Lynchburg - The Moore County News	4/4/2018	MOORE
Martin - Weakley County Press	4/5/2018	WEAKLEY
McMinnville - Southern Standard	4/6/2018	WARREN, Van Buren
Memphis - The Commercial Appeal	4/6/2018	SHELBY, Tipton and Fayette
Milan - The Mirror-Exchange	4/3/2018	GIBSON

NEWSPAPER NAME	DATE OF PUBLICATION	COUNTIES SERVED
Morristown - Citizen Tribune	4/6/2018	HAMBLEN
Mountain City - The Tomahawk	4/4/2018	JOHNSON
Nashville - The Tennessean	4/6/2018	DAVIDSON, Robertson, Sumner, Wilson, Rutherford, Cheatham, Dickson, Stewart, Houston and Montgomery
Nashville - Williamson AM	4/4/2018	WILLIAMSON
Newport - Newport Plain Talk	4/5/2018	COCKE
Oneida - Independent Herald	4/5/2018	SCOTT
Paris - Paris Post-Intelligencer	4/6/2018	HENRY
Parsons - The News Leader	4/4/2018	DECATUR
Pulaski - Pulaski Citizen	4/4/2018	GILES
Ripley - The Lauderdale County Enterprise	4/5/2018	LAUDERDALE
Rogersville - The Rogersville Review	4/4/2018	HAWKINS, Hancock
Savannah - The Courier	4/12/2018	HARDIN
Selmer - Independent Appeal	4/4/2018	MCNAIRY
Shelbyville - Shelbyville Times-Gazette	4/6/2018	BEDFORD
Smithville - Smithville Review	4/4/2018	DEKALB
Sparta - The Expositor	4/5/2017	WHITE
Sweetwater - The Advocate & Democrat	4/4/2018	MONROE
Tazewell - Claiborne Progress	4/6/2018	CLAIBORNE
Tiptonville - The Lake County Banner	4/4/2018	LAKE
Tracy City - Grundy County Herald	4/12/2018	GRUNDY
Tullahoma - Tullahoma News	4/6/2018	COFFEE
Union City - Union City Daily Messenger	4/4/2018	OBION
Wartburg - Morgan County News	4/4/2018	MORGAN
Waverly - The News Democrat	4/4/2018	HUMPHREYS
Waynesboro - The Wayne County News	4/4/2018	WAYNE
Winchester - The Herald Chronicle	4/6/2018	FRANKLIN
Woodbury - Cannon Courier	4/3/2018	CANNON

ATTACHMENT 28

REVISED PROJECT COST CHART

Section B. Economic Feasibility Item A, Project Costs Chart

Supplemental #2
Attachment 28
June 15, 2018
11:27 A.M.

REVISED

PROJECT COST CHART

A.	Construction and equipment acquired by purchase:		
	1.	Architectural and Engineering Fees	
	2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	$22,000
	3.	Acquisition of Site	
	4.	Preparation of Site	
	5.	Total Construction Costs	
	6.	Contingency Fund	
	7.	Fixed Equipment (Not included in Construction Contract)	$ 2,000
	8.	Moveable Equipment (List all equipment over $50,000 as separate attachments)	$ 3,000
	9.	Other (Specify) _____	
B.	Acquisition by gift, donation, or lease:		
	1.	Facility (inclusive of building and land)	$ 6,936
	2.	Building only	
	3.	Land only	
	4.	Equipment (Specify)_____	
	5.	Other (Specify) _____	
C.	Financing Costs and Fees:		
	1.	Interim Financing	
	2.	Underwriting Costs	
	3.	Reserve for One Year's Debt Service	
	4.	Other (Specify) _____	
D.	Estimated Project Cost (A+B+C)		
E.	CON Filing Fee		$15,000
F.	Total Estimated Project Cost (D+E)	TOTAL	$48,936

Supplemental #2
June 15, 2018
11:27 A.M.

AFFIDAVIT

STATE OF MS

COUNTY OF Madison

Michael Ford, being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. §68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

[signature], COO
SIGNATURE/TITLE

Sworn to and subscribed before me this 5th day of June (Month), 2018 (Year) a Notary

Public in and for the County/State of Madison / MS.

[signature]
NOTARY PUBLIC

My commission expires 3/8 (Month/Day), 2019 (Year).

STATE OF MISSISSIPPI NOTARY PUBLIC ID # 111676 DANETTE LINDSEY Commission Expires March 8, 2019 MADISON COUNTY